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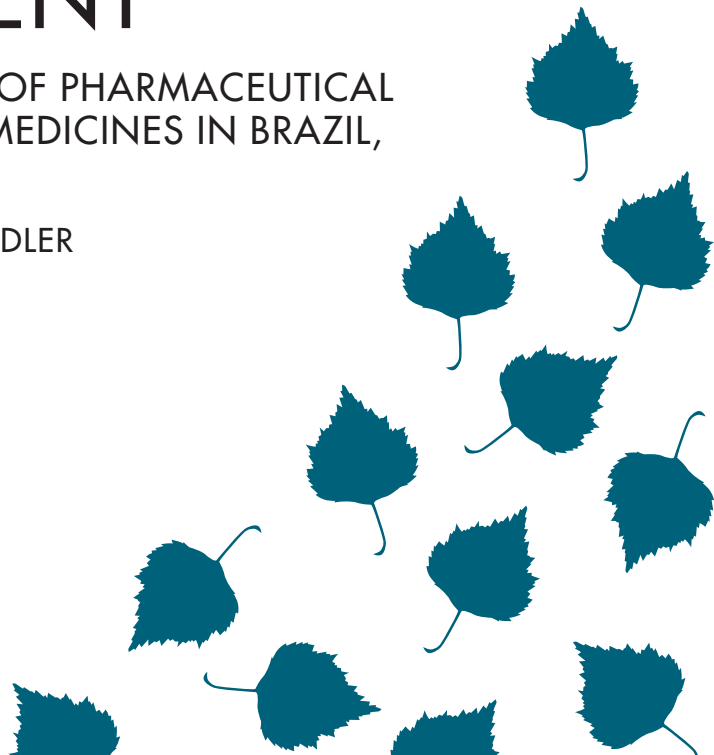


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THE ROLE OF PATENTS IN THE LATIN AMERICAN DEVELOPMENT

'MODELS OF PROTECTION' OF PHARMACEUTICAL
PATENTS AND ACCESS TO MEDICINES IN BRAZIL,
CHILE AND VENEZUELA

DHANAY MARÍA CADILLO CHANDLER



Ekonomi och samhälle
Economics and Society

Skrifter utgivna vid Svenska handelshögskolan
Publications of the Hanken School of Economics

Nr 273

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The Role of Patents in the Latin American Development

'Models of protection' of Pharmaceutical Patents and Access to
Medicines in Brazil, Chile and Venezuela

Helsinki 2014

The Role of Patents in Latin American Development: 'models of protection' of pharmaceutical patents and access to medicines in Brazil, Chile and Venezuela

Key words: intellectual property rights, pharma, patents, access to medicines, Latin America, human rights, essential medicines, public health, and universal coverage

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Hanken School of Economics

ISBN 978-952-232-237-1 (printed)
ISBN 978-952-232-238-8 (PDF)
ISSN-L 0424-7256
ISSN 0424-7256 (printed)
ISSN 2242-699X (PDF)

PREFACE

“El proceso de encuentro con la verdad requiere ante todo el asombro, seguido por un esfuerzo riguroso, sistemático, de profundizar ante las interrogantes que la realidad nos presenta: ¿qué es?; ¿para qué es?; ¿por qué es?; ¿cómo es?; ¿cuánto es?; ¿quién es?...”

“The process of meeting with the truth requires above all the wonder, followed by rigorous and systematic effort to deepen the questions brought by reality: what is? What is it for? Why is? How is? And who is it?” (Translated from the original text in Spanish)

Enrique Pérez Olivares

Una Visión de la Universidad – Palabras de Apertura del primer año lectivo 1999-2000 de la Universidad Monteávila.

This quote has been taken from my Alma Mater’s opening lection, which has inspired me the most within my professional development, and quite frankly this was probably the moment where my drive to challenge myself further in order to find the “truth” began. Throughout my studies in law I learned that besides receiving valuable academic education in law, this was not the sole purpose. Law is a path that takes you to look further into the evidence and cases that are presented before you. Being a lawyer equals to have the enormous privilege of making a difference into the matters and challenges one decides to take upon, and for me this research became that path. Always intrigued, always curious and always ambitious to keep on learning while knowing that my work could actually someday make a difference, be a contribution to something I believed could be achieved.

Researching about pharmaceutical patents and access to medicines taught me beyond my expectations. Finding a balance between patent protection and access to medicines seemed at the time as probably impossible and I feared that no feasible middle could be found, but little did I know since narrowing the dilemma to three countries and by allowing myself to look into public health policies would precisely allow me to find a possible answer –truth- that I was looking for. Having said this, I could have not done it without the guidance and support of many to whom I am very grateful with to have encountered along my journey to complete this doctoral project.

I would especially like to thank my supervisor Professor Marcus Norrgård and Professor Niklas Bruun for having guided me throughout the process, for taking with me the opportunity to learn more about pressing topics (Patents and IP) in faraway lands (Brazil, Chile and Venezuela). Your patience, encouragement, commitment, dedication, valuable comments and experience have not only help me shaping my research but have also inspired me. A heartfelt thank you goes to Professor Denis Borges Barbosa and Taina Pihjalarinne for having pre-examined my work and having provided me with the pointers necessary to improve this manuscript. Your various articles and books have also been an inspiration for my research, I would have not been able to carry out some of the most interesting discussions without your literature. I am also grateful with Professor Thomas Riis for accepting to be my opponent; it has been a real honour.

Another special thank goes to Professor Faustino Flamarique for your guidance and shared expertise to structure the Venezuelan Chapter of my research; and also to Monteávila University’s Rector Professor Joaquín Rodríguez Alonso for your encouragement to pursue postgraduate studies abroad. Thank you both for celebrating with me every step forward within my professional development.

Hanken School of Economics, the Department of Commercial Law and Accounting, and Hanken Foundation for Young Doctoral Students provided me with the infrastructure and financial means to successfully conclude my Doctoral Degree, and for this I am thankful. The Max-Planck Institute for Intellectual Property and Bayreuth Universität in Germany also welcomed me as a fellow researcher. I was fortunate to have had the privilege to research at these three great institutions where I was also enriched by working with professors and colleagues. Special thanks goes to Rosa Maria Ballardini and Pia Björkwall for your friendship and example throughout this journey. I would also like to take on the opportunity to thank my colleagues from the INNOCENT graduate school with whom I have the pleasure of sharing throughout significant part of the degree: Wim Helwegen, Liguozhang, Tanja Liljeström, Anu Pitkänen, Anette Alén, and Amina Agovic.

Within this journey I have required guidance from different parts of the world, therefore I would like to extend a heartfelt thank you to José Manuel Cousiño, Graeme Dinwoodie, Ansgar Ohly, Manuel Lovato, Francisco Allende, Ana María Pacon, Pedro Jedlika, José Ignacio Hernández, Andres Melossi, Marino Porzio, Holger Hestermeyer, Taniana Tobar, and Yovana Reyes Tagle.

On a more personal note, I cannot finish these acknowledgements without giving an earnest THANK YOU to my family (Venezuela and Finland) and friends' whom without their support, cheering and understanding I would not have been able to transit this path. Two phrases have particularly kept me going throughout the journey: "impossible nothing, the one who persevere wins and the sky is the limit;" and "everyone is entitled to succeed and to hear the applause, however one must earn these since success and applause are not for free." And by quoting these I can only thank my Mom for being my rock, one of my biggest fans and toughest critic because without your example, strength, love and guidance I would not be where I am, and because your teachings have helped in shaping me into who I am today. The second phrase is *in memoriam* of my father, who in a very short time taught valuable lessons that I will treasure forever since they have contributed to make me who I am today. I also need to extend a heartfelt thank you to my brother and Padrino for being there for me all the steps of the way. I look up to the two of you as examples as well of achievement and perseverance; and to my Grandmother for reminding me the value of faith and to continue believing in its greatness. I have been definitely blessed with excellent examples and an even greater family, thank you Lord for giving me the opportunity and presenting me with the means to achieve this degree.

Another earnest thanks goes to you Antti for being also my rock. Your support, love and endless patience kept me going, kept me grounded, but also kept me believing in myself. Whenever I felt like fainting you were there to cheer me, to read my manuscript and to point out the Spanglish that sometimes I missed. At last but not the least, special thanks to Rolando and Alex for bringing to me a piece of home into Finland; Begoña for the great discussions about Venezuelan IP law and your friendship; and to my German friends who have also been part of this journey.

Since the beginning of the research the premises in Venezuela have considerably changed, thus, I do not lose my hope in seeing a better future where my research could be taken into consideration to provide further understanding about IP law and public health care policy issued in my home country.

Dhanay M. Cadillo Chandler

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1 INTRODUCTION

Access to medicines, pharmaceutical patents, and public health are often in the news. The need to tackle pressing health needs, while providing adequate incentives to carry out research and development are also important aspects to take into consideration when addressing this challenge. Neither health concerns nor the strategies to balance intellectual property rights and access to medicines are determined by the geographical context. Thus, Latin American countries i.e. Brazil, Chile and Venezuela, even though geographically located in the same continent, deal with the challenges in a different and unique manner.

This book reviews the strategies or models of protection used in Brazil, Chile and Venezuela to balance both intellectual property rights (pharmaceutical patents) and access to medicines. Each country seems to have shaped their policies in accordance with their national priorities, whether these are motivated by health, political or commercial issues. This study portrays the different approaches followed in different national contexts despite all three having to implement the minimum standards of intellectual property protection according to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The outcome of the comparison of the policy implementations and the patterns followed by each of the analysed countries is without a doubt the main contribution of this academic study.

Before the TRIPS Agreement countries had the freedom to decide on whether or not to grant patent protection for medicines. Thus, most of the developing and least developed countries, now WTO member countries, did not provide patent protection for pharmaceuticals because they feared that patent protection would increase the price of pharmaceuticals, and hence, become an obstacle for the access to medicines.¹

TRIPS did not only settle minimum standards of protection, but it also contains certain flexibilities and/or exceptions such as parallel imports, compulsory licences and the bolar exception that could be used in determined cases to address national concerns. Further clarification on these flexibilities was sought in the DOHA Declaration, as will be analysed later on, since the declaration brought into the spotlight the newly created link and clash between public health concerns (e.g. access to medicines) and patent protection.²

On the one hand, patent protection represents an incentive for the pharmaceutical industry to carry out R&D for new and needed drugs.³ But on the other hand, patents, as the system of financing R&D, has been regarded as a

¹ See Hestermeyer, H., *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press, 2007) xxxiii-xxxiv.

² See DOHA Declaration See Declaration on the TRIPS Agreement and Public Health, World Trade Organization, WTO/MIN(01)/DEC/2 (20 November 2001) (Hereinafter Doha Declaracion)

³ Lemley, M., 'Ex Ante versus Ex Post Justifications for Intellectual Property' (2004) 71 *University of Chicago Law Review* 129, 1-67, at 2 <papers.ssrn.com/sol3/papers.cfm?abstract_id=494424> accessed 6 June 2013

flawed system due to the high costs transferred to the finalised product (medicine) thus deterring access to medicines.⁴

Patent protection allows the inventor to prevent others from making use, selling, producing or distributing the invention without his consent for a period of no less than 20 years.⁵ Moreover, these rights conferred by the patent grant seem to constitute the pharmaceutical industry's incentive to recoup the high costs associated with the R&D of a new drug.⁶ It is estimated that in recent years the costs derived from R&D of a new medicine up to the moment that it reaches the market are \$1.2 billion.⁷

During 2011 the pharmaceutical industry reported a 25% increase in costs to develop medicines, a fact that has made the industry review its practices in order to avoid costly trial failures.⁸ The cost for developing a new drug in 2002 was estimated at \$802 million according to the worth of the dollar in the year 2000,⁹ however, more recent studies have suggested a staggering cost of nearly \$1.5 billion dollars in 2011 for R&D costs per new molecule entities that actually reach the market.¹⁰ Even though the costs embedded in R&D are important within the discourse and aim at ensuring access to medicines, this doctoral research will not use either valuation or more sophisticated costs analysis than the ones provided within the aforementioned reports since depicting on these issues will require a separate study to address them in a proper manner. Thus, the focus of this research is of a more legal and social nature in the hope of reaching a conclusion that portrays possible solutions for achieving a balance between legislative reforms within patent law and health care and implementation issues securing access to essential medicines.

The cost of patented medicines has been considered to be one of the reasons limiting access to affordable medicines, and so to counteract these costs, scholars have come up with a number of propositions to help the pharmaceutical industry to cover for R&D costs so as to avoid transferring them to the finalised product. Among the proposed suggestions is the creation of a pool to fund R&D as a reward system instead of allowing the pharmaceutical companies to profit from

⁴ Love, J., and Hubbard, T., 'The Big Idea: Prizes to Stimulate R&D for New Medicines' (2007) 82 *Chicago Kent Law Review* 3, at 1520

⁵ Article 28.1(a) from the TRIPS Agreement Article 28.1(a) from the TRIPS Agreement Marrakesh Agreement Establishing the the World Trade Organization, Geneva, 15 April 1994, entered into force 1 January 1995, 1867 United Nations Treaty Series 3, annex 1C – Agreement on Trade-Related Aspects of Intellectual Property Rights (1994), Article 27 (1) (Hereinafter TRIPS Agreement) See Article 28.1(a)

⁶ Mishra, V., 'TRIPS, Patent Products and Pharmaceuticals' (2001) 36 *Economic and Political Weekly* 48, at 4464- 4467

⁷ Kowelle, J., 'Pharmaceuticals struggle to find next blockbuster drugs as R&D costs soar' *The Guardian* (London, 21 November 2011)

<www.guardian.co.uk/business/2011/nov/21/pharmaceuticals-drug-research-costs-rise> accessed 5 May 2013

⁸ Ibid

⁹ Di Masi, et al. 'The Price of innovation: new estimates of drug development costs' (2003) 22 *Journal of Health Economics* 2, 151-185, at 181

¹⁰ Mestre-Ferrandiz, et al. 'The R&D Cost of a New Medicine', Office of Health Economics (London, December 2012) <www.ohe.org/publications/article/the-rd-cost-of-a-new-medicine-124.cfm> accessed 20 February 2014

new medicines by setting high prices¹¹. In addition, a prize system incentivising innovation within the pharmaceutical industry has been envisaged,¹² but these possible solutions will be discussed in the concluding remarks. Given that pharmaceutical advancements are necessary to address health needs, some more pressing than others, as is the case with illnesses like HIV/AIDS, cancer, tropical diseases and even neglected illnesses all afflicting both the rich and the poor. The research assesses national health policies in its aim to identify those factors both deterring or enhancing access to medicines in each of the analysed countries.

The World Health Organization in its Medicines Strategy Reports, the UN Millennium Project 2005 and reports of several other scholars¹³ have identified external challenges influencing access to medicines, which are non-patent related. Among these, legislative delays, poor infrastructure, medical resources and governmental funding are to be noted.¹⁴

This study analysed and micro-compared the patent system, public health policy implementations and the political traditions prevalent in Brazil, Chile and Venezuela and allowed the identification of different approaches towards patent protection in each country. In brief, Brazil is at the moment the eighth largest world economy, among the first to implement TRIPS into their national law and a key player in protecting public health (HIV/AIDS). Chile, which is becoming part of the BRIC economies, has strong commercial relations with several trading partners, among them the United States of America, and currently possesses one of the best universal health care programmes in Latin America. Venezuela is politically active in a transitional period that is affecting both national and international legal commitments (legislative uncertainty). In addition, Venezuela is undergoing constant legislative health care reforms and even when large investments have been made within the health sector the country is still one of the countries in the region with the highest out of pocket expenditure on medicines.

Comparative law has been largely used in Latin America to shape its national laws and doctrines. Therefore, the results from the individual analysis of each country will be compared as to determine whether or not Venezuela could benefit from

¹¹ Suggestions made by Love, J., in the context of the World Health Assembly. Ngo, B., and New, W., "World Health Assembly: Groups Seek To Return Focus To 'Broken' Medical R&D System" (*Intellectual Property Watch*, 24 May 2013) <www.ip-watch.org/2013/05/24/world-health-assembly-groups-seek-to-return-focus-to-broken-medical-rd-system> accessed 25 May 2013

¹² See, Monteiro Veira, V. 'O prêmio como incentivo à criação de bens intelectuais na indústria farmacêutica' (2012) 6 *Revista Eletrônica Do IBPI – REVEL* <ibpibrasil.org/ojs/index.php/Revel/article/view/14> accessed 20 February 2014

¹³ At least within the Venezuelan context, Jaén was able to identify several factors deterring access to medicines even when her paper did not look at patent issues. See, Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?' in Jaén, M., Salvato, S., Daza, A., and Rivas, J., *Costo de la Salud en Venezuela: Gasto y Sostenibilidad Financiera del Sistema de Salud* (IEASA eds. Caracas, 2006) 30-31

¹⁴ UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines*, Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines. (Sterling, Va.: Earthscan, 2005) 29-30. WHO Strategy (DRAFT) WHO Medicines Strategy 2008-2013, Draft 8 (13 June 2008) 13 <www.who.int/medicines/publications/Medicines_Strategy_draft08-13.pdf> accessed 1st April 2014)

implementing a system similar to the ones used in either of the other two assessed countries. The overall result provided in this book will contribute to the Venezuelan doctrine as few books have been written about the national situation, and the suggestions within the conclusion could assist policy makers in both shaping and warranting the continuity necessary to achieve the balance between intellectual property protection and public health.

1.1. Purpose and Research Questions

The main purpose of this dissertation is to determine, through a comparative study, whether or not Venezuela could benefit from implementing a system similar to the ones used in either Brazil or Chile so as to balance intellectual property protection and access to medicines. Given that the minimum standards of intellectual property protection settled by the TRIPS Agreement are considered to be, by the current Administration, as a determining factor deterring access to medicines in Venezuela, this study also aims to demystify the aforementioned premise by identifying the real factors hampering access to medicines in Venezuela. Together with the main purpose, it is intended that the dissertation makes a literary contribution to Venezuela by analysing the current patent system from the perspectives of human rights and public health concerns. In doing so, the study becomes a multidisciplinary research integrating comparative law, legal, social and economical approaches.

Besides shedding light on current legal challenges in Venezuela related to pharmaceutical patents and access to medicines, this study intends to understand the impact derived from implementing the TRIPS Agreement in each of the countries in this study, and whether or not access to medicines was hampered by the implementation of the Agreement.

The core of the comparison aims at identifying the different ways to balance IP and access to medicines, if at all, and which model would work best in Venezuela. Furthermore, it is important to analyse the public health context in each country to determine, on the one hand, if pharmaceutical patents challenge access to medicines, and on the other if patented medicines are taken into consideration when implementing public health policy addressed to provide access to medicines. Given that the high costs of medicines has been pointed out to be one of the main factors jeopardising access to affordable medicines, it is also relevant to analyse if and how Brazil, Chile and Venezuela have made use of the flexibilities enshrined within the Agreement to address health concerns.

Subsequently, within the analysis, it is important to look at the particular issues prevalent in each country in order to gather a further understanding about the use and interpretation of TRIPS flexibilities at a national level. For instance, in Brazil both the compulsory licence regime and the prior consent mechanism were implemented to address public health concerns. The intellectual property law in Brazil rapidly became compliant with the TRIPS Agreement, and notwithstanding, the legislation also foresees that the controversial local working requirement, if unfulfilled, could be corrected by issuing a compulsory licence. Brazil's position towards protecting and ensuring access to essential medicines has been highly contested. Therefore it is required to analyse in more detail the challenges brought by each of the aforementioned mechanisms, while at the same time depicting on the evolution and content of the public health care framework

to determine if, at least in Brazil, TRIPS implementation has deterred access to medicines.

Chile seems to have embraced even higher levels of intellectual property protection by ratifying a free trade agreement with the United States of America, which admittedly brought an array of challenges in terms of compliance. Namely, the pharmaceutical linkage between the patent office and the national health institute, the extension of the term of patent protection and the provision on test data protection seem to be particularly controversial since these are deemed to jeopardise access to medicines in Chile. Therefore, it will be also necessary to analyse the public health framework to understand the level of governmental commitment in ensuring access to medicines in Chile, and also how patent protection can co-exist with public health policies guaranteeing universal coverage.

Lastly, Venezuela has been struggling to cope with the TRIPS Agreement since the withdrawal from the Andean Community. The Venezuelan context is by far among the most controversial in comparison with the other two countries analysed. In this respect, it will be indispensable to review the intellectual property framework according to both the Andean Community and the current system dating from 1955. The challenges derived from the implementation and withdrawal from the Andean Community, and the consequences from re-implementing the IP law from 1955 will be also analysed. Subsequently, analysing the public health policy will provide the necessary context to determine if either of the aforementioned IP laws challenge access to medicines in Venezuela.

Comparing the contexts and providing a solution will only be possible after having identified each of the strategies. This will then allow answering the main research questions of if and how could Venezuela benefit from implementing a similar strategy used in either Brazil or Chile to balance intellectual property rights and access to medicines.

1.2. Structure of the Thesis

This thesis is divided into seven chapters, and each chapter into several parts. The first chapter is comprised by an introduction to the study that is also divided into two parts. The first part presents the reader with an introduction to the study where the foundations for the research are laid down, such as purpose, rationale, research questions, structure and methodology. The second part provides the background for the research, specifically addressing basic concepts needed for the understanding of the discussion within the thesis. Specifically: what are intellectual property rights, their functions and development? What is public health? What is universal coverage? How are IP rights linked to public health and the relation of human rights with access to medicines?

The third, fourth and fifth chapters are the analytical chapters and are each divided into several parts. In these chapters the analysis on a country-by-country basis begins. Although each part presents different challenges, the structure of the analysis is similar in all of them. In this respect, each of the contextual investigations focuses on the patent system, rationale and evolution, challenges related to national and international commitments, impact on access to medicines and a brief overview on the public health system. Each part describes a

different context: the first part the Brazilian context, the second part the Chilean context and the third part the Venezuelan context.

The sixth and seventh chapters summarise the findings within the Brazilian, Chilean and Venezuelan contexts and also aim at identifying the strategies. The seventh chapter is divided into two parts, the first one discusses and compares the analysed contexts when its applicable, and the second one addresses the possibility of creating a side system of incentives for R&D to increase access to medicines where there is presently no sufficient supply. This last chapter presents the academic contribution that is the overall conclusion. In other words, whether and how Venezuela benefits from implementing or learning from one or the other contexts, and certain aspects that may constitute an advantage in tailoring TRIPS implementation in Venezuela.

Given the broadness and complexity within the IP vs. Public Health debate, this dissertation exclusively focuses on the debate existing in Brazil, Chile and Venezuela over pharmaceutical patents and access to medicines. Therefore, a reader who is familiar with the debate, the stakeholders' involved, the international framework and the agencies could skip part two of the introductory chapter and focus on the chapters dedicated to analysis and discussion.

1.3. Research Methodology

Comparative law has always the academic value of making us acquainted with other systems of law as a means of arriving at a better understanding of our legal institutions¹⁵

This is a micro-comparative¹⁶ study that analyses how different legal systems have solved a similar challenge. Specifically, it looks at which strategies for patent protection have been used in Brazil and Chile, aiming to obtain a better understanding of Venezuela's strategy. In this respect the study is conducted on the basis of two-stage approach¹⁷ using mainly comparative law as the research method, but also the legal dogmatic method is used to carry out the study. This is mainly a legal research, but also theoretical, empirical and social approaches towards pharmaceutical patents and public health are taken into consideration.

Vast literature has been written regarding TRIPS minimum standards. And yet there are countries such as Venezuela struggling to fully implement this Agreement. Developing countries have in common the fear that with a strong patent protection their chances of accessing affordable medicines will be diminished.

Therefore, the methodology used in the research aims to shed light on implementation issues related to pharmaceutical patents and access to medicines in Venezuela. Each country poses unique features embedded in its system due to

¹⁵ Landheer, B., 'Comparative Law in Latin-America' (1941) 27 American Bar Association Journal 75, at 77

¹⁶ "Micro-comparison generally refers to the study of topics or aspects of two or more legal systems" See de Cruz, P., *Comparative Law in a Changing World* (London: Cavendish Publishing, 1995) 7.2.4 at 224.

¹⁷ Ibid 7.3 at 231.

cultural, political traditions and history. Hence, health needs, public health, health care policies and services also vary in each country.

The two-stage approach comprises of description, identification and explanation or explanatory phase.¹⁸ Within the descriptive phase each country's legal frameworks,, institutions and concepts related to pharmaceutical patents and access to medicines will be described at a national level. At the international level the main Treaties and Conventions relevant to pharmaceutical patents and access to medicines ratified by each of the countries will be taken into consideration. The identification and explanatory phase aims to identify each country's strategy to balance IP rights and access to medicines, to thereafter discuss the findings among the systems.

As this research intends to analyse the internal legislation, health care policies, IP structure and history and the role of patents in economic development, it has been suggested that no understanding can be achieved of the need for pharmaceutical patents when only the social approach that looks to justify public health by all means is considered.¹⁹

Accordingly, comparisons can be useful if the legal institutions under investigation are natural and functionally comparable.²⁰ However, in the case of Latin America, and despite the countries being compared belonging to the same legal systems' family, civil law, it has been suggested how comparative law not only contributed to their development but also to moving "towards eclecticism for justifying the solutions proposed the basis for a new approach to comparative law in Latin America."²¹ This could contribute to creating legal irritants or transplants.²² However, it has been suggested that the idea of legal transplants is simply impossible because when a terminology or a rule is taken from a foreign jurisdiction this will change its meaning as soon as it is undertaken by the new jurisdiction.²³

Although there is a risk for transplanting foreign solutions into a foreign legal system, this study aims to shed light on implementation and tackling a balance between patent rights and access to medicines in Venezuela by looking at how other countries have done it and to analyse "if" there is something to learn from either or both of the foreign solutions.

¹⁸ de Cruz, P., *Comparative Law in a Changing World*, at 231

¹⁹ Ramírez, J., 'Patentes y Famacoeconomía' (2005) 32 *Revista Chilena de Derecho* 32, at 463-474 <www.puc.cl/derecho/html/publicaciones/busquedas.html> accessed 15 January 2013

²⁰ Zweigert, K., and Kötz, H., *An Introduction to Comparative Law*, 3rd Edición, (1998). And Also see Örücu, E., 'Developing Comparative Law', in Örücu, E., and Nelken, E. (eds.) *Comparative Law Handbook*, (1st edn. Oxford: Hart Publishing, 2007) at 46. "What the comparative lawyer looks at as tertiu comparationis could be the common functions between institutions and rules, the common goal they set out to achieve the problem, the factual situations they are created to solve or the solutions offered."

²¹ Kleinheisterkamp, J., 'Development od Comparative Law in Latin America', in Reiman, M., and Zimmermann, R. (eds.), *The Oxford Handbook of Comparative Law*, (1st edn, Clarendon Press: Oxford, New York, 2006) at 285.

²² Tuebner, G., 'Legal Irritants: How Unifying Law Ends up in New Divergences' (2001) *Varieties of Capitalism*, at 418

²³ Legrand, P., 'The Impossibility of Legal Transplants' (1997) 4 *Maastricht Journal of European and Competition Law*, 111-124 at 120

1.3.1. Comparative Law Method and Legal Dogmatic

Generally, comparative lawyers use comparative law to pursue legal reforms, but “academic comparative lawyers will use it to provide access to legal knowledge not only to promote a legal reform, or as a research tool, but to fulfil its essential task of furthering the universal knowledge and understanding of the phenomenon of law”²⁴

To make use of the comparative law method, it is necessary to identify similarities and differences among the systems analysed.²⁵ Thereafter, it is important to determine the main similarity among the Brazilian and Chilean systems in terms of TRIPS Agreement implementation and public health policies.

Scholarly research differs from practitioners or legislators’ research; the answer regarding the purpose of comparative law research varies with the activity carried out. In other words, even though “comparative law research is undertaken to improve knowledge of the law and understanding of the law in context”²⁶ the main goal or the ultimate goal is to discover which of the solutions given to a problem is the best one, possibly assessing the solution to that problem as a general principle of law.²⁷

On the one hand, the study looks at the similarity between Chile and Brazil as ‘successful’ in implementing the TRIPS Agreement and effective public health policies addressing access to medicines. On the other hand, it identifies the differences in “how” the Agreement was implemented and “how or if” either of the countries has made use of the flexibilities to tackle any particular health issue.

Comparative law can be seen as a method, a tool or a science in itself. As a method it is important to define “what to compare? And how to compare?”²⁸ It is also known that comparative law has worked giving a new direction to national legislations, therefore it is plausible to see the legislator’s task of investigating and finding a better solution, but this shall not be carried out in a simple manner. Scholars suggest that before adopting a foreign solution the question must be asked whether it has proven satisfactory in its country of origin, and whether it will work in the country where is proposed to be adopted.²⁹

Moreover, the comparison can also be carried out from the legal institutions point of view. This means that the comparison between similar or alike legal institutions can also take place within the framework of a piece of comparative law research besides solely taking into consideration the legal rules with the aim of harmonisation. Before identifying similar or alike legal institutions, the nature of these institutions needs to be re- assessed.

²⁴ Örücu, E., ‘Developing Comparative Law’, in Örücu, E., and Nelken, E. (eds.) *The Comparative Law Handbook*, (1st edn. Oxford: Hart Publishing, 2007) at 46

²⁵ Hoffman, M. B. and Berring, R.C. *International Legal Research: in a Nutshell* (Thomson/West: St. Paul, 2008) at 5-6

²⁶ Örücu, E., *Developing Comparative Law*, at 53

²⁷ Zweigert, K. and Kötz, H., *An Introduction to Comparative Law*, at 17. Within the idea of using the solution as a general principle of law the author intends to highlight how certain solutions can be found within the material compared

²⁸ Örücu, E., *Developing Comparative Law*, at 62

²⁹ Zweigert, K. and Kötz, H., *An Introduction to Comparative Law*, at 17

Whether or not comparative law works as a tool for legal reform, its main objectives are: 1. legal harmonisation to provide one's country with adequate social change through the use of a foreign system that shares the same challenge and 2. to promote social change through a foreign law that was designed to produce such an effect in that foreign country.³⁰

In the past, comparative law was 'praised for not being infected with the methodological disease.'³¹ However, it has been suggested that currently comparative research has become infected with the disease, since it is no longer about comparing rules and outcomes as functional solutions to universal challenges. Instead, the task goes beyond suggesting alternatives for the principal and even addresses what constitutes a better solution to a given challenge by discussing the limits of functionality.³²

Comparative law as a method presents limitations, since a comparison that is to be carried out between different legal systems should be described and understood as if they were one's own system. Hence, implying that one shall be fluent enough in the foreign language as translations can mean something completely different to what it really means within its original context, therefore translations should be avoided. Nevertheless, someone attempting to compare may only have the illusion of understanding and yet make the best of it by using adequate methodology.³³

According to the principle of functionality convergence is described as a stem for all other rules that determine a choice of law to compare, and only those that fulfil the same function are comparable.³⁴ Contrary to this, the thesis of convergence principle asserts that this principle allows law harmonisation and unification due to similar socio-economic structures.³⁵

Whereas functional equivalence seeks to solve similar structural problems even though the national legal order could be founded on diverse doctrinal traditions, what matters is to find which legal institution within the foreign system performs an equivalent function to the institution originally analysed.³⁶

In practice, lawyers constantly have to juxtapose; that is, compare different rules within their legal systems before reaching any practical or theoretical

³⁰ Kahn – Freund, O., 'On Uses and Misuses of Comparative Law' (1974) 37 *Modern Law Review* 1, at 2

³¹ Comparative law has worked successfully in the past, giving no methodological worries. However, trial and error seems to be a practice that aligns with the comparative law method success, as knowing which solution works best for a given problem heavily relies on the practical evidence and sense of appropriateness. See Zweigert, K., and Kötz, H., *Introduction to comparative Law*, at 33-34

³² Jansen, N., 'Comparative Law and Comparative Knowledge', in Reiman, M., and Zimmermann, R.(eds.) *The Oxford Handbook of Comparative Law*, (1st edn, Oxford University Press, New York, 2006) 308

³³ Legrand, P., 'How to Compare Now' (1996) 16 *Legal Studies*2, 232-242 at 236

³⁴ Id ut Supra Zweigert and Kötz, at 34

³⁵ Tuebner, G., 'Legal Irritants: How Unifying Law Ends up in New Divergences' (2001)*Varieties of Capitalism*, 417-442 at 419

³⁶ Örüci, E., 'Developing comparative Law', in *Comparative Law Handbook*, at 51

conclusions.³⁷ Hence, this investigation juxtaposes or uses the Brazilian system as the point of comparison given its tradition of making use of TRIPS flexibilities and leeway to protect and balance both IP rights and access to medicines. Thus, Brazil has actively taken part in most of the preparatory work before the Doha Declaration, and also became one of the first WTO Members in implementing the TRIPS Agreement into its own national system.

1.3.2. Legal Research and Legal Dogmatic

Legal-dogmatic research concerns researching current positive law as laid down in written and unwritten European or (inter)national rules, principles, concepts, doctrines, case law and annotations in the literature....³⁸

The legal dogmatic research method also encompasses legal research. On the one hand, both methods are concerned with the sources of law used in legal processes.³⁹ But on the other hand, they are concerned with the use of a theory to analyse determined rules.⁴⁰

The legal dogmatic research will present the analysis of the international, national and regional legal instruments related to pharmaceutical patents, public health and access to medicines in a systematic way, as well as the arguments embedded within the debate in both the national and the international context. This research intends to shed light on balancing strategies when implementing and protecting patent rights while at the same time ensuring peoples' access to affordable medicines.

Therefore, it is important not only to select the sources of law,⁴¹ but also to take into consideration the human rights approach when discussing and making relevant suggestions at the end of the study. Reviewing the relevant legislation, history and case law related to national health care policies and services within the countries is an attempt to address pharmaceutical patents and access to medicine from the point of view of the internal participants within the contexts analysed.⁴²

³⁷ Ibid at 2. "juxtapose," means "to put people or things together, specifically in order to show a contrast or a new relationship between them." See *Oxford Advanced Learner's Dictionary*, 7th edn, (Clarendon Press: Oxford) at 840

³⁸ Vranken, J., 'Exciting Times for Legal Scholarship' (2012) *Recht en Methode in onderzoek en onderwijs*, Aflevering 2 2012 <www.bjutijdschriften.nl/tijdschrift/rem/2012/2/ReM_2212-2508_2012_002_002_004/fullscreen> accessed 7 April 2014

³⁹ Idem. Also see, Vogenauer, S., 'Sources of Law and Legal Method in Comparative Law' in Reiman, M., and Zimmermann, R. (eds.), *The Oxford Handbook of Comparative Law*, (1st edn, Oxford University Press, New York, 2006) at 885

⁴⁰ Sadgren, C., 'On Empirical Legal Science', *Stockhol Institute for Scandinavian Law*, Edited by Peter Wahlgren, 445 <www.scandinavianlaw.se/pdf/40-17.pdf> accessed 15 February 2013

⁴¹ In many cases the legislator gives directions on how to rank and which are the sources of law within a system. For this purpose it is important to consult the constitutional text in each country part of the comparison. See Vogenauer, S., 'Sources of Law and Legal Method in Comparative Law' at 886-889. And also See de Cruz, P., *Comparative Law in a Changing World*, at 232-235.

⁴² Tuori, K., 'Self-Description and External Description of the Law' (November 2006) 2 *No Foundations: An Interdisciplinary Journal Of Law And Justice*, 27-43, 28

Throughout the analysis of the sources of law within the aforementioned context, it is expected to also take into consideration the facts as to delimit and survey the legal discourse when addressing i.e. the controversy around the prior consent mechanism in Brazil. Case law or court proceedings –when available will provide an insight in order to reach a better understanding of each context.

2 BACKGROUND OF THE STUDY: INTELLECTUAL PROPERTY AND PUBLIC HEALTH

This chapter intends to analyse the nature of both intellectual property rights and public health, primarily focusing on the intellectual property –pharmaceutical patents- vs. access to medicines debate in a general fashion before exploring the current situation in Brazil, Chile and Venezuela.

Within the access to medicines context, is it necessary to review not only basic concepts, but also the international framework behind this as a human right together with the most relevant organisations involved. In this respect, besides establishing what is to be understood for public health, its scope and its relation to the human right to health, the relationship and link will also be analysed between intellectual property rights and public health –access to medicines.

2.1. Defining Intellectual Property Right Through History

Intellectual property (IP) refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. (WIPO)

A patent is a document, issued, upon application, by a government office (or a regional office acting for several countries), which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorization of the owner of the patent. (WIPO, *Intellectual Property Handbook*)

Intellectual property and patents have been around for a long time. History points to the existence of patents since 1421 when the first patent was granted in Florence to Filippo Brunelleschi for his innovative solution to transporting by ship the carrara marble used to build Florence's Duomo.⁴³ The patent was granted to the ship that Brunelleschi had built to transport the marble through the Arno River. It has been said that the Florentine patent system sank with the ship due to conflicts between the major guilds, a decree enacted that limited the State-governed incentives for new crafts and technological innovations to tax exemptions alone among other reasons.⁴⁴

Later on in 1474, the Venetian Republic began granting patent protection in the form of import licences and private issuance to encourage guilds dominating commerce and arts to come up with technological innovations.⁴⁵ Guild rules are said to have led to the creation of the Statute of Venice in 1474. Letters of patent were also granted in the United Kingdom, in this respect, the Statutes of

⁴³ Nard, C. A., and P. Morriss, A., 'Constitutionalizing Patents: From Venice to Philadelphia' (2006) 2*Review of Law and Economics*2, 223-320, at 233

⁴⁴ Idem Nard, C. A., et al in 'Constitutionalizing Patents' quoting Bugbee, B. *Genesis of American Patent and Copyright*(Washington, D.C.: PublicAffairs Press – 1964)

⁴⁵ Moser, P., 'Patents and Innovation: Evidence from Economic History' (winter 2013) 27*Journal of Economic Perspectives*1, 23-44, at 25

Monopolies was created in 1624 to encourage manufacturing growth and to lure skilled workers to live in England.⁴⁶

One of the most interesting patent monopolies granted in the form of patent was the Darcy patent; given as an import licence to bring playing cards into the British market. Patents granted for vinegar, starch and playing cards were the most well known letters of patent.⁴⁷ The enactment of the Statute of Monopolies in England was an indication of the growing importance of trade within the country's economy, and the willingness to foster innovation, which eventually allowed a step forward into industrial production.⁴⁸ Initially, patents in England were considered a "matter of condescension" from the Crown and not a matter of private rights. However, there was a shift in this position allowing the country to gain from the export of technology as competitors used letters of patent as a source of information since judges often required adequate description or sufficient statement of the conception as justification for the monopoly granted.⁴⁹ The "disclosure" or full description of the invention became a formal requirement under the 1852 Patent Law Amendment Act, thus settling the foundation and importance of dissemination of knowledge via the patents disclosure.⁵⁰

While some countries moved forward by providing patent protection – during the nineteenth century- others had not even considered adopting patent law or simply abolished the systems. For instance, the Netherlands abolished in 1869 its patent system, Switzerland had no formal patent system until 1907, Germany also revoked its patents system from 1817 and in Denmark patent protection was only granted for a period of five years.⁵¹ Amid a lack of legislative consensus or protection among nations, the need to harmonise to a certain extent led countries to agree about patent protection under the framework of the Paris Convention in 1883. Globalisation and the move towards an industrialised world are said to have preceded the Paris Convention. In particular history seems to recall an international exhibition of inventions held in 1873 in Vienna, the success of which was jeopardised by the fact that neither the Austria-Hungary Empire offered adequate legal protection, nor were many of the visiting countries willing to put on display their inventions due to the lack of protection.⁵²

Between 1873 and 1883, three important developments took place prior to signing and approving the Paris Convention for the Protection of Industrial Property. Following the close failure of 1873's innovation exhibition fair, the government via special law granted temporary protection to all foreigners taking part in the exhibition including trademarks and industrial design. Then, the Congress of Vienna during the same year agreed upon a Patent Reform, where a

⁴⁶ Craig Nard (ed.) 'History and Architecture of the Patent System' in *The Laws of Patent* (2nd. Edition, Aspen Publishers: 2010) 1-55, at 9-11.

⁴⁷ Idem.

⁴⁸ Cornish, W., and Llewelyn, Intellectual Property: Patents, Copyright, Trad Marks and Allied Rights (Sweet & Maxwell- London: 2010) 124-125

⁴⁹ Idem Cornish, W., et al. 'Intellectual Property' 125-126

⁵⁰ Nard, C., 'History and Architecture of the Patent System', 14-15

⁵¹ Moser, P., 'Patents and Innovation', 25-26. Also See Gontijo, C., 'Changing The Patent System From The Paris Convention To The Trips Agreement The Position Of Brazil', (Dec. 2005) 26 *Global Issue Papers*, 1-32, 5. <www.fdcl-berlin.de/fileadmin/fdcl/Publikationen/GIP_Gontijo-Patente.pdf> accessed 20 March 2014

⁵² WIPO, *Intellectual Property Handbook* (2nd. Edition, 2008) 1-488, 241

series of principles were elaborated that aimed to portray what an efficient and useful patent system should be like. And finally, the International Congress on Industrial property was held in Paris during 1878 where the attending countries were compelled to agree upon a harmonised system for the protection of industrial property under the frame of a union.⁵³ Eventually in 1883, eleven States –initially- signed the Paris Convention for the Protection of Industrial Property. This is said to be one of the most successful Conventions that harmonised intellectual property legislation, and its success is attributed mainly to the fact that only general principles were settled yet countries had enough freedom to decide on the terms of protection.⁵⁴

The Paris Convention is the basis for the Patent system as we know it today. Even when the principle of national treatment,⁵⁵ the right of priority,⁵⁶ importation, local working requirement and compulsory licences⁵⁷ are among the most important provisions, nothing within the convention defines patents or invention or refers to patentability requirements. In terms of patent protection, the provision in Article 4 *bis* foresees the independence of patents that needs to be interpreted in the broadest sense possible:

This principle is to be understood in its broadest sense. It means that the grant of a patent for invention in one country for a given invention does not oblige any other member country to grant a patent for invention for the same invention. Furthermore, the principle means that a patent for invention cannot be refused, invalidated or otherwise terminated in any member country on the ground that a patent for invention for the same invention has been refused or invalidated, or that it is no longer maintained or has terminated, in any other country. In this respect, the fate of a particular patent for invention in any given country has no influence whatsoever on the fate of a patent for the same invention in any of the other countries.⁵⁸

In the context of patent protection, several treaties, conventions and agreements have been ratified. Namely, the Community Patent Convention, the Patent Cooperation Treaty, the European Patent Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights are among the important international frameworks. However, for the purpose of giving context to the discussion on pharmaceutical patents and access to medicines only those

⁵³Idem.

⁵⁴See Gontijo, C., ‘Changing The Patent System’, 6-7

⁵⁵ Article 2, and 3 from the Paris Convention for the Protection of Industrial Property, as last revised at Stockholm. 21 UST 1583, 828 UNTS 305

⁵⁶ Article 4 from the Paris Convention

⁵⁷ Article 5 from the Paris Convention

⁵⁸ WIPO, ‘Intellectual Property Handbook’, 245. Also see Article 4 *bis* from the Paris Convention:

“(1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.

(2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, both as regards the grounds for nullity and forfeiture, and as regards their normal duration.

(3) The provision shall apply to all patents existing at the time when it comes into effect.

(4) Similarly, it shall apply, in the case of the accession of new countries, to patents in existence on either side at the time of accession.

(5) Patents obtained with the benefit of priority shall, in the various countries of the Union, have a duration equal to that which they would have, had they been applied for or granted without the benefit of priority.”

agreements and conventions will be referenced that are relevant to the discussion.⁵⁹

Modern patent law grants protection for inventions that meet with the patentability requirements. This protection allows the right holder to prevent others from using, distributing, selling or producing the patented product without the owners consent.⁶⁰ In general terms, patent rights grant a monopoly, since they allocate exclusive rights to the right holder. Nevertheless, this exclusivity is limited in time and territory. Patent protection shall be granted without discrimination of the field of technology for a period of 20 years from the date it was applied for. Limitation to the territory where the patent has been granted requires a patent holder to pursue patent protection in at least each of the countries where the patented product or process intended to be commercialised, unless the countries have ratified the relevant international Treaties and Conventions.⁶¹

Accordingly, patents can be assessed from the utilitarian approach perspective. This approach facilitates the understanding of reproducibility and enforceability as part of elements defining patents. The inventor would not feel compelled to disclose an invention if patent protection were not available, as within the utilitarian fruits approach patents are a reward for the inventor for the fruits of his work that is translated into public disclosure as the price for protection.⁶²

2.2. What is Public Health?

Besides intellectual property rights, certain aspects of public health such as its definition, scope, classification and terminology require addressing before identifying or making the connection between pharmaceutical patents and access to medicines.

In 1948, after the Second World War, the United Nations committed to promoting international cooperation not only in the economic, social, cultural and educational fields but also in the field of health.⁶³ In this respect, Article 57 from the United Nations Charter foresaw the creation of specialised agencies to

⁵⁹ For more detailed information on the evolution of intellectual property right and historical facts, see Nard, C. A., and P. Morriss, A., 'Constitutionalizing Patents: From Venice to Philadelphia' (2006) 2 *Review of Law and Economics* 2, 223-320; Moser, P., 'Patents and Innovation: Evidence from Economic History' (winter 2013) 27 *Journal of Economic Perspectives* 1, 23-44; Craig and see Nard, C. (ed.) 'History and Architecture of the Patent System' in *The Laws of Patent* (2nd. Edition, Aspen Publishers: 2010) 1-55

⁶⁰ Cornish, W., 'Intellectual Property', 7-8, and 144-148

⁶¹ WIPO, *Intellectual Property Handbook* (2nd. Edition, 2008) at 17-22

⁶² Aly Crowne, E., 'The Utilitarian Fruits Approach to Justifying Patentable Subject Matter', (2011) 10 *John Marshall Review of Intellectual Property Law* 753, 754-763

⁶³ Article 13(1)b, Charter of the United Nations, 24 October 1945, 1 UNTS XVI <www.refworld.org/docid/3ae6b3930.html> accessed 24 September 2013. "...promoting international co-operation in the economic, social, cultural, educational, and health fields, and assisting in the realization of human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion."

assist Member Countries in solving or assessing challenges related to the realisation of human rights.⁶⁴

The World Health Organization (hereinafter WHO) is a specialised agency of the United Nations system⁶⁵ that has become the leading organisation in the discussion about health related topics, and provides Member Countries with guidelines on global health, as well.⁶⁶In a general fashion, the WHO defines “health systems” according to what citizens should be provided with. In this respect, the World Health Report from 2000 foresees that “all the activities whose primary purpose is to promote, restore or maintain health”⁶⁷are to be included within the health system definition. The aforementioned report also establishes that a health care system has many variables determining the extent to what should or should not be covered. Nevertheless, this implies responsibilities beyond improving people’s health. Preventing people from enduring financial hardship or avoiding self-impovertishment due to high costs derived from illness, is also considered to be essential for an adequate performance or coverage.⁶⁸

Despite several studies having shown differences between health systems in Latin America, the financial aspect embedded in these systems seems to be one of the determining factors influencing this classification. For instance, the WHO takes into consideration countries’ level of income, whereas other scholars have provided broader classifications based on the governmental role; in other words, from more statutory to less statutory.

Thus far, the National Health Services Systems (NHS), National Social Insurance Systems (NHIS) and Mixed National Health Systems (MNSH) are the three categories that most commonly describe the health care frame available in Latin America. The National Health Services Systems (NHS) can be understood as the systems where central government institutions play an important part in the provision of health care services, and at the same time social health insurance institutions are non-existent or only represent a small part in the financing of the system.⁶⁹ National Social Insurance Systems (NHIS) are those systems where one or more social insurance institutions play an important role in the provision of health care services that cover only 50% or more of the total population. And Mixed National Health Systems (MNSH) are characterised by the fact that public sector institutions play a small part in the provision of health care services, the coverage of the mandatory social health-insurance covers less than one-third of

⁶⁴ Articles 13, 57, and 63 from the Charter of the United Nations

⁶⁵ Resolution 124.II General Assembly, Second Session, from 15 November 1947
<www.un.org/documents/ga/res/2/ares2.htm> accessed December 2012

⁶⁶ El Said, M. K., Public Health related TRIPS-plus provisions in the bilateral trade agreements: A Policy Guide for negotiators and implementers in the WHO Eastern Mediterranean Region, World Health Organization, Regional Office for the Eastern Mediterranean, (2010), 109

⁶⁷ *The World Health Report 2000 – Health systems: Improving Performance*, World Health Organization, Geneva (2000) 1-206, at 5 <www.who.int/whr/2000/en/whr00_en.pdf> accessed 10 September 2013

⁶⁸Ibid at 8.

⁶⁹ Suárez – Berenguela, R., ‘Health system inequalities in Latin America and the Caribbean: Findings and Policy Implications’ (2000) Working paper prepared for the Health and Human Development Division of the Pan American Health Organization-World Health Organization, at 7 <www1.paho.org/english/hdp/hdd/suarez.pdf> accessed 14 September 2013

the total population and the out of pocket expenditure on health services is very high.⁷⁰

Having said this, it has been also highlighted that the WHO classifies most of Latin American countries' national health systems as Mixed National Health Systems given that none of them provide real universal coverage as offered by i.e. European health care services.⁷¹ Within the systems' definition and scope, independent of their level in the classification, universal coverage seems to be the ideal scenario for health care. Thus, it means that everyone should have access to appropriate promotive, preventive, curative and rehabilitative health care when they need it and at an affordable cost.⁷²

The WHO in the World Health Assembly from 1975 through Resolution WHA 28.66 encouraged countries to implement drug policies aligned with their needs. Defining each country's essential medicines together with the formulation of strategies for appropriate procurement of quality drugs according to health needs and providing both education and training in various elements of pharmaceutical programmes were addressed within the Resolution as well.⁷³ According to the WHO, deterring or improving access to medicines within the public health discourse is commonly challenged by the price of medicines, but these do not solely influence access to medicines as several other aspects interfere in the cycle as is addressed below.

The UN Millennium Project in its report from 2005 pointed out six of the most important barriers to access of medicines. By describing challenges to both existing medicines and to the development of affordable new ones, these barriers have been divided into two categories.⁷⁴ First, inadequate national commitment and human resources, lack of finance on behalf of the international community and persistent lack of coordination of international aid have been identified as the barriers deterring access to existing medicines.⁷⁵ And secondly, the report pointed out that the barriers related to the development of affordable drugs the facts that the Agreement on Trade Related Aspects of Intellectual Property Rights (hereinafter TRIPS Agreement) may block access to affordable medicines and the inadequacy of the current incentive structure to promote R&D of medicines.

Defining certain terminologies to delimit the scope of the discussion may provide guidance to both the reader and stakeholders. Therefore, the WHO defines Essential medicines as those needed to fulfil the population's health care priorities and those that also are intended to be available within the context of functioning health systems at all times, in the required dosage forms, with

⁷⁰ Ibid

⁷¹ Ibid

⁷² *Achieving Universal Health Coverage: Developing the Health Financing System*, Technical Briefs for Policy-Makers, World Health Organization, WHO/EIP/HSF/PB/05.01, Number 1(2005).

⁷³ See further, World Health Organization, *How to Develop and Implement a national drug policy* (Second Edition, Updates and replaces. Guidelines for Developing a National Drug Policy 1998. Geneva: 2001) at 1-83 <archives.who.int/tbs/ndp/s2283e.pdf> accessed 14 September 2013

⁷⁴ UN Millennium Project 2005, 'Prescription for Healthy Development: Increasing Access to Medicines', Report of the Task force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines, (Sterling, Va.: Earthscan -2005) 29

⁷⁵ Ibid 29-30

assured quality and at affordable prices for individuals to purchase them.⁷⁶ At the same time, ‘access’ has been defined by the United Nations Development Group ‘as having drugs continuously available and affordable at public or private health facilities or drug outlets that are within one hour’s walk of the population.’⁷⁷ Both ‘access’ and ‘essential medicines’ are important terms used within the public health general discourse, therefore the definition provided aims at facilitating the reader with an understanding of the scope of both terminologies.

2.2.1. Access to Medicines as part of the Human Right to Health

The race towards achieving universal coverage so as to ensure people’s access to essential medicines brought to the spotlight the discussion on access as part of the human right to health.⁷⁸ Pharmaceutical patents among other things have been identified as a barrier to adequate public health⁷⁹ that just a few countries within the developing world can provide. Thus far, access to essential medicines seems to be considered as a derivative right within the broader sense of the human right to health.⁸⁰ Human Rights Law has made a significant contribution to the codification of the human right to health and its scope.⁸¹

Since 1945, the Charter for the United Nations in various articles has overseen health and the creation of specialised agencies to achieve or promote solutions to challenges related to it.⁸² Later, in 1966, the International Covenant on Economic, Social and Cultural Rights (hereinafter ICESCR) specified or codified the right to health. In this respect, Article 12.1 from the ICESCR establishes that State Parties recognised the right of everyone to the enjoyment of the highest attainable standard of physical and mental health including treatment, prevention and control of epidemic, endemic, occupational and other diseases.⁸³

⁷⁶ Harlem Brundtland, G.. and Moore, M., foreword to A joint study by the WHO and the WTO Secretariat, *WTO Agreements and Public Health*, World Health Organization/ world Trade Organization (2002) <www.wto.org/english/res_e/booksp_e/who_wto_e.pdf> accessed 10 September 2013. Also see, World Health Organization, ‘Essential Medicines: Definition’, <www.who.int/medicines/services/essmedicines_def/en/index.html> accessed 7 December 2012

⁷⁷ United Nations Development Group, ‘INDICATORS for Monitoring the Millenium Development Goals: Definitions, Rationale, Concepts, and Sources’ United Nations, (New York, 2003) 35 <www.undp.or.id/mdg/documents/MDG%20Indicators-UNDG.pdf> accessed 7 December 2012

⁷⁸ Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/RES/12/24 (2 October 2009) at para. 7

⁷⁹ *The world health report - Health systems financing: the path to universal coverage*, World Health Organization (Geneva, 2005) <whqlibdoc.who.int/whr/2010/9789241564021_eng.pdf> accessed 14 September 2013

⁸⁰ P. Marks, S., ‘Access to Essencial Medicines as a component of the Rights to Health’ in Clapham, A., and Robinson, M. (eds.) *Realizing the Right to Health- Swiss Human rights Book Vol. 3* (2009) 80-99

⁸¹ Philippe Cullet, ‘Patents and medicines: the relationship between TRIPS and the human right to health’ (2003) 79 *International Affairs* I, 139 – 160

⁸² See Articles 13(1)b, 55(b), 57, and 62 from the Charter for the United Nations.

⁸³ See Preamble and Article 12(1), International Covenant on Economic, Social and Cultural Rights, Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, in force 3 January 1976

However, the aforementioned convention was unclear regarding the meaning of the highest attainable standard of health.⁸⁴ In 2000, the Committee on Economic, Social and Cultural Rights (CESCR) in its twenty-second session settled the parameters for understanding the right to health in the document 'The right to the highest attainable standard of health: 11/08/2000. E/C.12/2000/4. (General Comment 14).' In this regard, not only are access to essential medicines, primary health care attention and minimum health services among others to be provided to country nationals,⁸⁵ but also Member Countries' duty to fully comply with the ICESCR is to be upheld unless they lack the necessary resources to accomplish the minimum health goals.⁸⁶

The UN - Commission on Human Rights in Resolution 2001/33 recognised that 'access to medication is a key element for achieving full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'⁸⁷ Consequently, the right to health seems to have a particular importance in the context of pandemics such as HIV/AIDS, malaria and tuberculosis. Therefore, governments need to be encouraged to provide essential medicines while at the same time ensuring citizens minimum standards of health care. Scholars have highlighted the importance that non-state actors have in the sector of public health, since their role in finding donors to finance health programmes has perhaps given better results than in any other field.⁸⁸

Diverse initiatives have been developed towards achieving a wider understanding of the challenges faced by the developing world in regards to health needs and also at finding solutions to these challenges. The Global Strategy and Plan of Action on Intellectual Property Rights, Innovation, and Public Health, the Millennium Goals, the Bill and Melinda Gates Foundation HIV/AIDS Program and The World Bank-WHO initiatives are among the few projects based on the importance of the human right to health.

For instance, in 1997 the World Bank published the 'Health, Nutrition and Population Strategy' that focused on health outcomes and emphasised support for improved health system performance.⁸⁹ Later, in 2007, this strategy was updated, but the ultimate objective of the World Bank is to 'is to improve health conditions of the people in client countries, in the context of its overall strategy for poverty alleviation.'⁹⁰

⁸⁴ Hein, W., and Kohlmorgen, L., 'Global Health Governance: Conflicts on global Social Rights' (2008) 8*Global Social Policy* 1, 80-108, at 82

⁸⁵ The right to the highest attainable standard of health: Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights, UN – Economic and Social Council, General Comment No. 14 E/C.12/2000/4 (11 August 2000) para 43

⁸⁶ *Ibid* para 47

⁸⁷ Commission on Human Rights Resolution 2001/33, Access to Medication in the context of pandemics such as HIV/AIDS, 71st Meeting (23 April 2001) para 1

⁸⁸ Hein, W., and Kohlmorgen, L., 'Global Health Governance' at 83-85

⁸⁹ World Bank Group, Improving Effectiveness and Outcomes for the Poor in Health, Nutrition, and Population: An Evaluation of the World Bank Group Support since 1997, The World Bank (Washington, D.C. - 2009) 1-185, 5

⁹⁰ Healthy Development: The World Bank Strategy for Health, Nutrition, and Population Result, The World Bank (Washington, D.C. - 2007) 1-216, 11

Another international convention to take into consideration when analysing the Human Right to Health is the International Covenant on Civil and Political Rights (hereinafter ICCPR). This is a multilateral treaty adopted under the United Nations umbrella during its General Assembly on 16 December 1966, which came into force in March 1976. This treaty is particularly relevant not only because it has been ratified by 152 nations, but also because it complements the human right to health by protecting the right to life.⁹¹

A broad interpretation of the 'right to life' extends to the basic conditions of life,⁹² which includes access to life-saving drugs or essential medicines since States must protect by law, fulfil and prevent violations of people's right to life.⁹³ It has been argued that by denying access to life-saving drugs, this right could be in jeopardy given that the right to life evolved beyond 'the right to be free from arbitrary killing'.⁹⁴

Human rights, in general, are intended to be applicable to every human being without any kind of discrimination.⁹⁵ However, the human right to health does not only seem to be affected by globalisation,⁹⁶ but it is also dependent on the realisation of other human rights i.e. education, privacy and non-discrimination.⁹⁷

On the one hand, globalisation is reported to bring development into nations' economies, but on the other hand it has been suggested that this also creates a 'new global order where corporate and financial interests prevail over the interests of the population.'⁹⁸ Therefore, it is advisable to implement legislative reforms on the basis of the human rights- approach so as to ensure a lesser negative impact on peoples' rights, given that, human rights intertwine with the relationship between individuals and the state by creating rights for one and obligations for the state to fulfil.⁹⁹

Alleged national policies based on human rights ensure a governmental commitment towards the realisation of the right to health in a way that is internationally recognised, which at the same time creates legal responsibilities for the State.¹⁰⁰

⁹¹ Article 6.1 from UN General Assembly, International Covenant on Civil and Political Rights, 16 December 1966, United Nations, Treaty Series, vol. 999, 171

<www.unhcr.org/refworld/docid/3ae6b3aa0.html> accessed 10 January 2013

⁹² Gammie, B., 'Human Rights Implications of the Export of Banned Pesticides' (1994) 25 *Seton Hall Law Review*, 558 et seq. 585

⁹³ Hestermeyer, H., 'Access to Medication as a Human Right', (2008) 8 *Max Planck UNYB*, 148-155.

⁹⁴ Gammie, B., 'Human Rights Implications', at 558 et seq. 582

⁹⁵ Gruskin, S., et al. 'From Conceptualization to Realization: A Human Right to Health' (may 2010) *Letters 3 Hastings Center Report* 40, 4-6.8

⁹⁶ Evans, T., 'A Human Right to Health?' (2002) 23 *Third World Quarterly* 2, 197 – 215

⁹⁷ Arras; and Fenon; replying to Gruskin et al. 'From Conceptualization to Realization', at 6

⁹⁸ Evans, T., 'A Human Right to Health?', at 209-210

⁹⁹ V. Hogerzeil, H., 'Essential Medicines and Human Rights: What can they learn from each other?' (2006) 84 *Bulletin of the World Health Organization*, at 371 - 375

¹⁰⁰ Crewe, M., 'The HIV/AIDS Epidemic and Human Rights Responses', in Clapham, A., and Robinson, M. (eds.) *Realizing the Right to Health- Swiss Human rights Book Vol. 3* (2009) 277-286, at 278

The rights-based approach to development describes situations not simply in terms of human needs, or of developmental requirements, but in terms of society's obligation to respond to the inalienable rights of individuals. It empowers people to demand justice as a right, not as charity, and gives communities a moral basis from which to claim international assistance where needed.¹⁰¹ (Kofi Annan, Secretary-General of the United Nations)

In terms of the right-based approach, specifically in medicines programmes, the need to follow basic principles of non-discrimination and equality has been highlighted since these can feature health care conditions for all groups of the population, thus making it easier to determine different health needs within various groups.¹⁰² To determine the needs and the implementation of this approach, recognition of everyone's right to the enjoyment of the highest attainable standard of health within national Constitutions¹⁰³ seems to be an important question that needs asking when assessing governmental commitment to the right to health.

Accepting access to medicines as part of the human right to health does not seem to be troublesome for nations, since reportedly several national constitutions already acknowledge these rights within the internal framework. However, this recognition is neither a guarantee nor an essential step taken by many countries.¹⁰⁴

The human right-based approach has an impact on national legislation, since the State is the main guarantor for the fulfilment of this right. For instance, basic health needs are deemed health rights, and priorities need to be settled within the health sector for government to allocate sufficient financial resources to comply with their commitments.¹⁰⁵

Despite increasing the governments' accountability due to the human right approach to health, it has been suggested that given the nature of their business that the pharmaceutical industry should also take into consideration this approach.¹⁰⁶ The industry's role towards the realisation of the right to health will be examined in the conclusion.

Thus far, access to medicines seems to be recognised as part of the human right to health as defined by several international agreements. Moreover, implementing measures to ensure access to medicines according to scholars derives from the

¹⁰¹ Annual Report of the Secretary-General on the Work of the Organization, UN Doc. A/53/1 (1998), para 174, at 23

<www.preventionweb.net/files/resolutions/N9825109.pdf> accessed 10 January 2013

¹⁰² Oldring, L., and Jerbi, S., 'Advancing a Human Rights Approach on the Global Health Agenda', in Clapham, A., and Robinson, M. (eds.) *Realizing the Right to Health- Swiss Human rights Book* Vol. 3 (2009) 100-108, at 106

¹⁰³ V. Hogerzeil, H., 'Essential Medicines and Human Rights', at 373

¹⁰⁴ V. Hogerzeil, H., and Mirza, Z., *The World Medicines Report 2011: Access to Essential Medicines as Part of the Right to Health*, WHO Doc. WHO/EMP/MIE/2011.2.10 (3rd Edition, 2011) at 6

¹⁰⁵ Asher, J., 'The Right to Health: A Resource Manual for NGOs' (August 2004) *The Commonwealth Medical Trust*, at 22-23

¹⁰⁶ Schroeder, D., 'Does the Pharmaceutical Sector Have a Coresponsability for the Human Right to Health?' (2011) 20 *Cambridge Quarterly of Healthcare Ethics*, 298-308

state's legal obligation to do so. In addition, there is the suggestion that 'access' needs to be reflected as a priority within budget planning and health care organisation since access cannot be guaranteed independently from a functioning health care system.¹⁰⁷ Another important aspect embedded within the implementation of a human right approach to health is its enforceability within national courts. Accordingly, with the report on the World Medicine Situation from 2011, in several countries national health policies have been challenged as a direct consequence of not fulfilling the legal obligation of providing access to essential medicines.¹⁰⁸

Health as a human right has been recognised fundamentally as the responsibility of the state. However, globalisation as already highlighted seems to have redressed the burden into the international community and other non-state actors due to countries receiving influence from trade regimes, loans and development assistance.¹⁰⁹

2.3. The Relationship between Intellectual Property Rights and Public Health (access to medicines)

With the creation of the World Trade Organization (hereinafter WTO) in 1994 its member countries also ratified a series of Agreements, among these, the Agreement on Trade Related Aspects of Intellectual Property (hereinafter TRIPS), which linked public health to intellectual property rights by extending protection to all fields of technology. This part aims at providing the reader with some general information necessary to understand the context, relevance and impact on public health issues and access to medicines presented in the discussion. Therefore it is important to address the creation of the WTO, the importance of the TRIPS Agreement and Doha Declaration in the context of patents.

2.3.1. WTO and TRIPS Agreement

The WTO was created in 1994 through the Marrakesh Agreement during the well-known Uruguay Round. The Organisation became operational in 1995 and does not only deal with trade rules between nations, but is also responsible for setting international trade rules.¹¹⁰

Annexed to the Marrakesh Agreement Establishing the World Trade Organization, a total of 12 Agreements were to be mandatorily ratified by nations becoming Members of the WTO. Among these, the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (hereinafter TRIPS Agreement), that was ratified by 158 Members on 2 February 2013, re-

¹⁰⁷ Ely Yamin, A., 'Not Just a Tragedy: Access to Medication as a Right under International Law' (2001) 21 *Boston University International Law Journal*, 325- 371, at 327.

¹⁰⁸ V. Hogerzeil, H., and Mirza, Z., *The World Medicines Report 2011*, at 6. Also see, V. Hogerzeil, H., et al. 'Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?', 368 *The Lancet*, (July -2006) 305-311

¹⁰⁹ Asher, J., 'The Right to Health', at 64

¹¹⁰ *Globalization, TRIPS and access to pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3, World Health Organization, Geneva, WHO/EDM/2001.2, at 1.

conceptualised intellectual property rights as trade issues¹¹¹ when minimum standards of protection were not only established but also extended to all fields of technology, including the pharmaceutical field.¹¹²

This part of the analysis will assess both the content of the TRIPS Agreement relating to patents and public health and its impact on WTO Member Countries. Nations, by acceding to the WTO, also agreed upon extending the term of protection for a period of 20 years¹¹³ both to products and processes, as they now were contracting parties.¹¹⁴ This new provision was also binding for developing and least-developed nations that did not provide patent protection for the length settled for all fields of technology, since the Paris Convention allowed Member Countries to legislate over the fields of technology that should be subject to patent protection.¹¹⁵

To a certain extent some scholars perceive the TRIPS Agreement as an “agent of change in the health sector”¹¹⁶ since patents for pharmaceutical products and processes were now to be granted. Allegedly in the past, this sector was excluded from patentability due to public or social concerns in terms of countries’ need to ensure access to medicines at a low price and also to protect the national pharmaceutical industry.¹¹⁷

The Agreement, besides extending patent protection to all fields of technology and stating patentability requirements, does not define what an invention is. In this respect, the lack of consensus on a universal definition has been highlighted, which is not indicative of an omission or a loophole in the TRIPS Agreement.¹¹⁸ Allegedly, this is not the only definition that is not provided by the Agreement: the same Article 27(1) aims at defining inventions by giving their patentability requirements –new, inventive step and capable of industrial application- but

¹¹¹ Dreyfuss, R., ‘TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis’, in Pogge, T., Rimmer, M. and Rubenstein, K. (eds.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, New York, 2010) 35-55, at 35

¹¹² Marrakesh Agreement Establishing the the World Trade Organization, Geneva, 15 April 1994, entered into force 1 January 1995, *1867 United Nations Treaty Series* 3, annex 1C – Agreement on Trade-Related Aspects of Intellectual Property Rights (1994), Article 27 (1) (Hereinafter TRIPS Agreement)

¹¹³ Article 33 from TRIPS Agreement

¹¹⁴ Article 27(1) from TRIPS Agreement. The non-discrimination principle is embedded within the Agreement since patents cannot be refused on basis of the field of technology.

¹¹⁵ Paris Convention for the Protection for Industrial Property, as Amended in September 28, 1979, WO020EN, Article 1(4).

¹¹⁶ Cullet, P., ‘Patents and medicines’, at 145

¹¹⁷ Roffe, P., Spennemann, C. and von Braun, J., ‘From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health’, in Roffe, P., Tansey, G., and Vivas-Eugui, D. (eds.) *Negotiating Health: Intellectual Property and Access to Medicines* (Earthscan, UK-USA, 2006) 9-26, at 13

¹¹⁸ Correa, C., ‘Implementing the TRIPS Agreement in the Patents Field: Options for Developing Countries’ *1 The Journal of World Intellectual Property* 1 (1998) 75-99, at 76

none of these are defined, except for the ‘inventive step’ that can be taken as ‘non-obvious’.¹¹⁹

Article 27(2) and (3) also foresee patentability exceptions, namely those “contrary to public order or morality, including to protect human, animal or, plant life or health” animals, and members may also exclude from patentability diagnostic and/or therapeutic and surgical methods.¹²⁰

Articles 7 and 8 give the first link to public health within the Agreement, since the need to balance rights and obligations and the importance to promote social and economic welfare as well as to protect public health are acknowledged.¹²¹

Although, the Agreement intends to provide a harmonised intellectual property regime with minimum standards of protection, it also allows Member Countries to tailor their national systems to implement the Agreement.¹²² Some developing countries seemed to have implemented stronger IP protection, reportedly as a strategy to attract the pharmaceutical industry to innovate, transfer and disseminate its technology.¹²³ Nevertheless, exceptions are also foreseen by the Agreement to protect public health, correct anticompetitive practices and to address national emergencies.

Besides allowing Members to take the necessary measures to protect both public health and public interests, the Agreement in Articles 30 and 31 settles the exceptions for patent protection. Namely, Article 30 entails limited exceptions to these exclusive rights as long as the measures taken do not unreasonably conflict with the normal exploitation of the patent or with the legitimate interests of the patent owner, taking into account the legitimate interests of third parties as well.¹²⁴

The other exception foreseen within the Agreement is the compulsory licences regime, also known within the Agreement’s Article 31 as ‘Other use without Authorization of the Right Holder.’ Accordingly, country members are entitled to enact compulsory licences to predominantly supply the internal market¹²⁵ and

¹¹⁹ Footnote 5 from Article 27(1) of the TRIPS Agreement. See also, Correa *Ut supra* at 82. Arguably the fact that patentability requirements are not defined ‘opens some room for flexibility at the national level’ as indicated by Correa.

¹²⁰ Article 27(2) from TRIPS Agreement states, “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to ... health, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

¹²¹ Article 7-8 from the TRIPS Agreement. See also Globalization, TRIPS and access to pharmaceuticals, WHO Policy Perspectives on Medicines No. 3, World Health Organization, Geneva, WHO/EDM/2001.2

¹²² Dreyfuss, R., ‘TRIPS and Essential Medicines’, at 37

¹²³ Wanis, H., ‘Agreement on Trade-Related Aspects of Intellectual Property Rights and Access to Medication: Does Egypt Have Sufficient Safeguards Against Potential Public Health Implications of the Agreement’ (2010) 13 *The Journal of World Intellectual Property* 1, 24-46, at 25-26

¹²⁴ Article 30 from TRIPS Agreement, “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

¹²⁵ Article 31 (f) from the TRIPS Agreement

after adequately remunerating the right holder.¹²⁶ In general terms, even when a compulsory licence has been enacted, “the right holder shall be paid adequate remuneration taking into account the economic value of the authorization” as pointed out by Article 31 (h) from the TRIPS Agreements. However, the Agreement also foresees an exception to this rule settled within the same Article part (k) from where it could be inferred that the aforementioned compensation does not necessarily take place under the terms initially foreseen within Article 31(h) since the amount of the compensation may need to be taken into consideration when correcting anti-competitive practices.¹²⁷ The original Agreement –draft- brought along a gap in members’ ability to take measures to address public health or national emergencies given to Article’s 31 (b) requirement to pursue voluntary licence from patent holders before actually enacting compulsory licences.¹²⁸

Following the TRIPS Agreement, countries began lobbying for further clarification in terms of the flexibilities. Two particular cases seemed to have played an important role in the move towards recognising public health concerns in the years to come. During 1997 the South African Government modified its National Drug Policy in a manner favourable to compulsory licences and parallel imports in their aim to tackle the HIV/AIDS crisis, but both the U.S. government and the U.S. pharmaceutical industry strongly opposed such implementation by arguing that it was an abrogation to patent rights and subsequently a breach of TRIPS.¹²⁹ The USTR placed South Africa on the Special 301 reports watch list for two years in a row (1998-1999) and later on also withheld trade benefits for a selection of products that were already approved within the Generalized System of Preferences (GSP) as a method of pressure on South Africa to back down from implementing the revised National Drug Policy.¹³⁰ Given the media attention, and the work of activists, the U.S. Government shifted its policy towards South Africa in a manner consistent with South Africa’s need to achieve greater access to essential medicines.¹³¹

In 2000 the U.S. Government called for consultations with Brazil due to the implementation of the working requirement within its IP legislation, which, if

¹²⁶ Article 31 (h) from TRIPS Agreement

¹²⁷ Article 31 (k) from TRIPS Agreement

¹²⁸ Article 31 (b) from TRIPS Agreement. See Also, Mitchell, A.D., and Voon, T., “The TRIPS Waiver as a recognition of public health concerns in the WTO”, in Pogge, T., Rimmer, M., and Rubenstein, K. (eds.), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press, New York, 2010) 56-76, at 59-61. The Agreement in its final version included a waiver on the requirement for the party pursuing a compulsory license to obtain authorisation from the right holder for such use in cases of national emergency, or other circumstances of extreme urgency. Regardless of the waiver, the right holder must be notified as soon as possible about the measure.

¹²⁹ Fischer, William W., and Rigamonti, Cyrill, ‘The South Africa AIDS Controversy A Case Study in Patent Law and Policy’ *The Law and Business of Patents* (Harvard Law School, Updated 2005) 3-5 < cyber.law.harvard.edu/people/tfisher/South%20Africa.pdf > accessed 10 March 2014

¹³⁰ Idem at 7. During 1998 the South African Pharmaceutical Association brought their complaint about the revised National Drug Policy before the High Court of South Africa. The industry challenged the constitutionality of the legislation, allegations that were later on dismissed by the High Court. (Fischer, W. et al)

¹³¹ Idem at 8-9. Also See Dicey, V., ‘AIDS drug imperialism’ (1999) 42 *The Monthly Journal of the Socialist Party* <www.socialismtoday.org/42/aids.html> accessed 15 January 2013

unfulfilled, would suffice for the government to enact compulsory licences and/or parallel trade to satisfy the internal market.¹³² These two cases portrayed the conflict of interests, sometimes still prevalent, between the interests of the pharmaceutical industry on the one hand and on the other with the duty to implement the TRIPS Agreement in a manner consistent with each country's national needs (i.e. to supply the internal market to grant access to essential medicines). The local working requirement in Brazil is not strictly to address public health issues, as will be assessed later on within the Brazilian chapter, and instead the aforementioned provision is settled within the frame of compulsory licences.

Thus far it has been established that the TRIPS Agreement does not only settle minimum standards of protection, but also foresees exceptions to patent rights. More attention shall be given to both the Doha Declaration and other flexibilities conceived to address public health concerns among other national interests. Thus far, TRIPS flexibilities can be summarised as compulsory licences, parallel imports and early working exceptions or Bolar exception. These have been defined as:

- Compulsory Licences can be understood as “the authorization given by the State to a third party to exploit a patented invention, generally against a remuneration to the patent holder, and these may be granted according to national laws on several grounds, such as emergency, public interests, non-working of the invention, anticompetitive practices and dependency of patents.”¹³³
- Parallel imports refer to the situation “when a product made legally (i.e. not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g. the trademark or patent owner).”¹³⁴
- Regulatory exception or ‘Bolar exception’ “allows manufacturers of generic drugs to use the patented invention, without the patent owner's permission and before the patent protection expires, for the purpose of obtaining marketing approval from public health authorities. Generic producers are thus able to market their versions almost as soon as the patent expires.”¹³⁵

It has been suggested that developing and the least-developed countries have taken advantage of TRIPS' options and safeguards, for instance, in determining when intellectual property rights have been exhausted either at a national or an

¹³² Roffe, P., et al. 'From Paris to Doha', at 17, Also See WTO Dispute DS199

<www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm> accessed 14 March 2014

¹³³ Correa, C., 'Public Health and Intellectual Property Rights' (2002) 2*Global Social Policy*3, 261-278, at 268

¹³⁴ WTO Glossary<www.wto.org/english/thewto_e/glossary_e/parallel_imports_e.htm> accessed 14 March 2014

¹³⁵ WTO Agreement and Public Health: a joint study by the WHO and the WTO Secretariat (WTO Secretariat, 2002) 44. <www.wto.org/english/res_e/booksp_e/who_wto_e.pdf> accessed 14 March 2014

international level depending on each Members' preference.¹³⁶ TRIPS- Agreement flexibilities, as these set of exceptions became known, were object to further negotiations and clarifications in the Doha Round since these link intellectual property rights with public health concerns. The flexibilities were deemed necessary given that IP protection was now available for medicines as well.

2.3.2. Doha Declaration on the TRIPS Agreement and Public Health

Following the TRIPS Agreement WTO Members began pushing for further clarification in terms of the use of TRIPS flexibilities and also for international recognition of public health concerns. As part of the analysis, it is important to address the structure, content and importance of the Doha Declaration on the TRIPS Agreement and Public Health and the Decision implementing paragraph 6 from the Doha Declaration and its following amendment.

In 2001 during the Fourth Ministerial Conference in Doha, public health concerns were recognised by WTO Member States in the 'Declaration on the TRIPS Agreement and Public Health' (hereinafter Doha Declaration or Declaration) and also in the Doha Ministerial Declaration.¹³⁷ The Doha Declaration is structured in seven paragraphs that assess the Agreement's provision relevant to public health concerns, bringing also to the spotlight the need to modify the compulsory licence regime as first established. In this respect, HIV/AIDS, tuberculosis and malaria are recognised as some of the epidemics that afflict the most; hence further R&D is needed.¹³⁸

The Doha Declaration is considered as a milestone in the debate between TRIPS and access to medicines, since it makes the agreement both development and public health-friendly in terms of interpretation.¹³⁹ The Declaration is said to include similar language as to the one found in the Submission by the African group¹⁴⁰ before the Ministerial Conference, together with other developing and least developed countries, which have been perceived as a relevant issue to facilitate both the interpretation and the implementation of the Agreement since protecting public health is still a major concern.¹⁴¹

Paragraph 5 of the Declaration does not only honour the commitments within the Agreement, but also recognises and clarifies to a certain extent the use of

¹³⁶ Deere, C., *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Clarendon Press: Oxford, 2008) at 75

¹³⁷ *Doha Declaration on the TRIPS Agreement and Public Health*, World Trade Organization, WTO Doc. WT/MIN(01)/DEC/2, (1 November 2001), and Also see, *Doha Ministerial Declaration*, World Trade Organization, WTO Doc. WT/MIN(01)/DEC/1, (14 November 2001)

¹³⁸ Paragraph 1, Doha Declaration WT/MIN(01)/DEC/2

¹³⁹ Nagah, A., 'TRIPS and Public Health: What should African Countries Do?' *African Trade Policy Centre*, Working Paper N° 49 (January 2007) at 3

¹⁴⁰ Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/296 (June 2001) at 22 <commerce.nic.in/wto_sub/trips/sub_Trips-ipcw296.htm> accessed 10 February 2013

¹⁴¹ Yu, P. K., 'The Objectives and Principles of the TRIPS Agreement' (2009) 46 *Houston Law Review* 979 <www.peteryu.com/correa.pdf> accessed 10 January 2013

compulsory licences, parallel imports and the leeway given to Member Countries to determinate what constitutes a national emergency.¹⁴² However, Doha Declaration as it was adopted, is said to contain stronger language than the one originally used within the drafts prior to the final version. Working groups had reported to have had disagreed on two key issues, namely the use of “access to medicines” instead of “public health” and with regard to paragraph 4’s choice of words in allowing member countries to take measures to protect public health without breaching the Agreement.¹⁴³ Developing nations requested the phrase, “Nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health”¹⁴⁴ to be included within the final document, but instead during the negotiations the phrase “...the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” was approved for the final draft.¹⁴⁵

Another important issue addressed within the Doha Declaration referred to the difficulties in making effective use of compulsory licences by Members with no or insufficient manufacturing capability. In this regard, in paragraph 6 the Council for TRIPS was instructed to find a solution to the problem and report back to the General Council by 2002.¹⁴⁶

The least developed countries had the prerogative to fully implement the Agreement, specifically patent protection for pharmaceutical products, by 2016.¹⁴⁷ This provision within the Doha Declaration is consistent with Article 65 (4) from the TRIPS Agreement.¹⁴⁸ However, scholars have highlighted that both the ambiguity embedded within paragraph 7 in terms of the so-called ‘mailbox provision’ and whether or not countries had to either grant ‘exclusive marketing rights’ or implement the mailbox provision before the end of the transitional period are important issues to clarify.¹⁴⁹

In light of the TRIPS Agreement’s Article 70 (9), Member Countries that did not provide patent protection for pharmaceutical products, but granted marketing approvals for a new product through its national health agency, had to grant

¹⁴² Paragraph 5 (a)-(d) Ministerial Conference, Forth Session, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 20 November 2001 (Herein after Doha Declaration)

¹⁴³ Watal, J., ‘From Punta del Este to Doha and beyond: Lessons from the TRIPS negotiation process’ (2011) 3 *The WIPO Journal* 1, 24-35, at 30

¹⁴⁴ Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, General Council for Trade-Related Aspects of Intellectual Property Rights IP/C/W/312, WT/GC/W/450 (4 October 2001) at 1
<www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm> accessed 10 January 2013

¹⁴⁵ Paragraph 4 from Doha Declaration

¹⁴⁶ Paragraph 6 from Doha Declaration

¹⁴⁷ Paragraph 7 from Doha Declaration

¹⁴⁸ Article 65(4) from TRIPS Agreement, “To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.”

¹⁴⁹ Frederick, A., ‘WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries’ Study Paper 2a, United Kingdom Commission on Intellectual Property Rights, (February 14, 2002) 1-69, at 11<ssrn.com/abstract=1924420>accessed 15 January 2013

exclusivity for a period of 5 years.¹⁵⁰ However, on the 8 July 2002 the General Council decided to waive exclusive marketing rights for the Least Developed Country members.¹⁵¹

Allegedly, the terminology ‘exclusive marketing rights’ was unusual in the legal jargon and became introduced with the TRIPS Agreement, presenting Member Countries with a new challenge. Exclusive marketing rights, after following the Oxford dictionary’s definition, strictly mean that a product that obtained a marketing approval in a country making use of the transitional period can only be commercialised in that country by the applicant. However, this is not to prevent third parties from producing, exporting and commercialising the product in foreign markets.¹⁵²

2.3.3. From the Decision on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health to the TRIPS Agreement Amendment

Despite WTO Members having received the Declaration as a positive step towards ensuring adequate use of TRIPS flexibilities, the interpretation of paragraph 6 became worrisome as little information about its procedure was provided.¹⁵³ Hence, different positions and interests preceded long negotiations before reaching consensus over the implementation of Paragraph 6 of the Doha Declaration.

Furthermore, on the 30 August 2003 in the General Council, WTO Member States adopted Decision WT/L/540 that settled rules to issue compulsory licences to export patented medicines to countries with no manufacturing capacity.¹⁵⁴ This Decision is considered to have broken new ground in clarifying the relationship

¹⁵⁰Article 70(9) from TRIPS Agreement, “Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.”

¹⁵¹ General Council, Decision of 8 July 2002, Least-Developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, World Trade Organization, WTO Doc. WT/L/478, 12 July 2002

¹⁵² UNCTAD-ICTSD, ‘Resource Book on TRIPS and Development: An Authoritative and practical guide to the TRIPS Agreement’ (Cambridge University Press, July 2005) at 774 <www.iprsonline.org/unctadictsd/ResourceBookIndex.htm> accessed 20 January 2013

¹⁵³ Lalitha, N., ‘Doha Declaration and Public Health issues’ (September 2008) 13 *Journal of Intellectual Property Rights* 401-413, at 405

¹⁵⁴ General Council, ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health Decision 30 August 2003’, World Trade Organization, WTO Doc. WT/L/540 (1 September 2003). (hereinafter Decision WT/L/540) <www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm> accessed 20 January 2013. Note that the TRIPS Agreement in Article 31(f) did not foresee compulsory licences for export purposes, therefore countries with no manufacturing capacity were not able to obtain pharmaceutical products produced under the compulsory licence’s scheme in a foreign country.

between TRIPS and public health and also because it ratified country members' 'freedom' to issue compulsory licences to address public health emergencies.¹⁵⁵

The aforementioned Decision contains three waivers besides establishing the notification system and settling the conditions to benefit or to be fulfilled before intending to make use of compulsory licences under Paragraph 6 of the Doha Declaration. This Decision basically waives 'the obligation in 31(f) that compulsory licences shall be used predominantly to supply the internal market, and the obligation in 31(h) for the Importing Country to pay adequate remuneration to the right holder, and the obligation in 31(f) allowing re-export of important pharmaceuticals among members or a regional trade agreement if half of its members are least developed countries.'¹⁵⁶

Thus far, it has been established that the scope of Decision WT/L/540 is pharmaceutical products as defined in paragraph 1 (a). The same text defines both eligible Importing Members¹⁵⁷ and Exporting Members.¹⁵⁸ However, it is not enough to become either an Importing or an Exporting Member by notifying the TRIPS Council if the conditions settled in the Decision are not met.

In this respect, the notification submitted by an eligible importing Member shall (i) specify the means and expected quantities of the products(s) needed,¹⁵⁹ (ii) confirmation that the eligible importing Member-other than least-developed country Member- has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question,¹⁶⁰ and (iii) the confirmation that the country intends to grant a compulsory licence or that the country has already been granted one given that the product is patented within the territory.¹⁶¹

On the other hand, the compulsory licence issued by the Exporting Member shall contain (i) only the amount necessary to meet the needs of the eligible Importing Member, therefore it can only manufacture the highlighted amount under this

¹⁵⁵ Vandoren, P., and Van Eeckhaute, J., 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6*The Journal of World Intellectual Property*6, at 779-793

¹⁵⁶ Kommerskollegium National Board of Trade, The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems (2008) 1-100, at 23

¹⁵⁷ Paragraph 1(b) from Decision WT/L/540 defines eligible importing Member as "any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;"

¹⁵⁸ Paragraph 1(c) from Decision WT/L/540 defines eligible exporting Member as "a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member."

¹⁵⁹ Paragraph 2(a)(i) from the Decision WT/L/540

¹⁶⁰ Paragraph 2(a)(ii) from the Decision WT/L/540

¹⁶¹ Paragraph 2(a)(iii) from the Decision WT/L/540

licence which also needs to be exported in its totality;¹⁶² (ii) products produced under the licence shall be clearly identified as being produced under the system, taking into consideration that labelling, packaging, and shaping needs to be different from the products commercialised outside the system, prices cannot increase due to strict labelling and marking rules;¹⁶³ and (iii) the licensee shall post on a website¹⁶⁴ both the quantities being supplied to each destination and the distinguishing features of the products before the shipment begins.¹⁶⁵

As of today, Canada and Rwanda are the only countries making use of the system set out by paragraph 6 of the Doha Declaration.¹⁶⁶ Accordingly, 33 countries have opted out to use the system as importers, and 11 agreed to use it exclusively in cases of extreme urgency.¹⁶⁷

To effectively make use of the mechanism set out in Paragraph 6, exporting Members need to adapt their patent legislations so as to grant compulsory licences for exporting purposes, since it is not enough to have the WTO Decision allowing Members to grant these kind of licences. Allegedly, one of the reasons behind developing and least-developed Members' impossibilities in making use of the system relates to the implementation of the aforementioned system within its national laws.¹⁶⁸ Despite the mechanism representing an effective flexibility to tackle access to medicines, scholars have identified its complexities as a drawback in itself for the system. For instance, potential eligible importing Members are able to purchase generics from India at reasonable prices without having to enact a compulsory licence to carry out such an import and also due to both implementation issues and confusing rules in terms of the adequate remuneration that needs to be paid.¹⁶⁹

This notification system was intended to be temporary until the amendment to the agreement became permanent in 2005.¹⁷⁰ On 6 December 2005 the General

¹⁶² Paragraph 2(b)(i) from Decision WT/L/540

¹⁶³ Paragraph 2(b)(ii) from Decision WT/L/540

¹⁶⁴ Footnote 7 from Decision WT/L/540 allows the licensee to post the aforementioned information on a website maintained by the WTO as well

¹⁶⁵ Paragraph 2(b)(iii) from Decision WT/L/540

¹⁶⁶ See Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health from Rwanda in WTO Doc. IP/N/9/RWA/1 (19 July 2007), and from Canada in WTO Doc. IP/N/10/CAN/1 (8 October 2007)

<[docs.wto.org/dol2fe/Pages/FE_Search/FE_S_Soo6.aspx?Query=\(%20@Symbol=%20ip/n/9/*%20\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](http://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_Soo6.aspx?Query=(%20@Symbol=%20ip/n/9/*%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#)>, and <[docs.wto.org/dol2fe/Pages/FE_Search/FE_S_Soo6.aspx?Query=\(%20@Symbol=%20ip/n/10/*%20\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](http://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_Soo6.aspx?Query=(%20@Symbol=%20ip/n/10/*%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#)> accessed 1 February 2013

¹⁶⁷ Correa, C., 'Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,' *Health Economics and Drugs*, Series N° 016 (Universidad de Buenos Aires, April-2004) 1-49, at 11-12

<apps.who.int/medicinedocs/en/d/Js6159e/> accessed 20 February 2013

¹⁶⁸ Hestermeyer, H., *Human Rights and the WTO: The Case of Patent and Access to Medicines* (Clarendon Press: Oxford, 2007) at 270

¹⁶⁹ *Ibid* Hestermeyer at 271-272

¹⁷⁰ Paragraph 11 from Decision WT/1/540 "This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing

Council passed the Amendment of the TRIPS Agreement, so as to integrate Article 31*bis* into the Agreement that comprised the notification system and the terms for compulsory licences to work.¹⁷¹

For the amendment to come into force, it is necessary for two-thirds of the Members to ratify it. Thus far only 71 countries have ratified it from a total of 120 Country Members.¹⁷² Nevertheless, the waivers of the Decision have been in use since 30 August 2003.¹⁷³

its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1)”

¹⁷¹ General Council, ‘*Amendment of the TRIPS Agreement- Decision of 6 December 2005*’, World Trade organization, WT Doc. WT/L/641 (8 July 2005)

<www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 20 January 2013

¹⁷² *Member accepting amendment of the TRIPS Agreement*, World Trade organization.

<www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 20 January 2013

¹⁷³ Kommerskollegium National Board of Trade, ‘*The WTO Decision on Compulsory Licensing*’, at

3 INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN BRAZIL

Even though Brazil, Chile and Venezuela are found within South-America, each of these countries portrays a very different economical, socio-political and legislative context. On the one hand, Brazil and Chile are commonly recognised because of their level of development, and on the other, Venezuela seems to be constantly acknowledged for its political instability. The following chapter will describe and analyse in brief each of the country's political contexts to allow the reader to understand the challenges embedded in both intellectual property and public health contexts.

It is widely known that Brazil is an emerging and leading economy among many other developing countries. After twenty years of military dictatorship, Brazil has moved towards an open economy. Accordingly, political and neo-liberal economical reforms were carried out during the years of repression. This allowed society to reach considerable governmental representation that at the same time, forced the State to have higher levels of social participation.¹⁷⁴

The military rule in Brazil began in April 1964 when the armed forces ousted Joao Goulart from the presidency. In 1975, after several years of military dictatorship, social and political repression, the new constitutional reform allowed limited, political and social activity.¹⁷⁵ At this time, Brazilian politicians began drafting the 1988 political constitution, which guided the country towards progress by ending the previous abusive period where human rights violations had taken place.¹⁷⁶ This constitutional reform was seen as an important factor in achieving the new democracy. Social needs were acknowledged, and therefore the system sought to include peoples health concerns by aiming to build a comprehensive public health care system based on universal coverage as a social benefit as given by Brazil's constitution.¹⁷⁷

Brazil has a large geographic extension with a population that extends to over 190 million inhabitants, according to the data collected in the official census by the

¹⁷⁴ Nervo Codato, A., 'A Political History of the Brazilian transition from military dictatorship to democracy' (2006) 2*Revista de Sociologia e Política*, 83-106

¹⁷⁵ Henry, J., 'Brazil's 1964 Military Coup: The Political Foundations of Regressive Development' (2006) *Submerging Markets*, 1-15. Also see is S. Henry, *The Blood Bankers: Tales from the Global Underground Economy*, (New York: Four Walls, Eight Windows, December 2003) at 417

¹⁷⁶ Gomes Borges, B., 'O Dever de Efeitição da Justiça Transicional na Redemocratização Brasileira', Masters Thesis, Pontificia Universidade Católica do Rio Grande do Sul (2009) 7 <http://www3.pucrs.br/pucrs/files/uni/poa/direito/graduacao/tcc/tcc2/trabalhos2009_2/bruna_borges.pdf> accessed 17 November 2012

¹⁷⁷ Hunter, W., and Borges Subiyama, N., 'Democracy and Social Policy in Brazil: Advancing Basic Needs, Preserving Privileged Interests' (2009) 51 *Latin American Politics and Society* 2, 35

Instituto Brasileiro de Geografia e Estatística –IBGE in 2010.¹⁷⁸ Recent data shows a population increase of nearly four million up to 2012.¹⁷⁹

This chapter, besides presenting the reader with a brief historical overview, seeks to analyse the origins of intellectual property protection, the constitutional approach of these rights, the social function embedded within the constitutional framework and to later on assess the public health tradition and current developments related to pharmaceutical patents in Brazil. In other words, despite having established the relationship between patents and access to medicines in the previous chapter, it is important to understand the level of governmental commitment towards the fight against HIV/AIDS. Public health concerns seemed to have played an important role in Brazil's decision to enact a compulsory licence and to create the mechanism known as *Anuência Previa* or Prior Consent.

3.1. National Intellectual Property and Public Health Policies Evolution in Brief

In respect to intellectual property rights, Brazil was one of the first countries to provide IP protection via internal legislations. Patent law was first foreseen in the *Alvará de D. João VI* (The charter of D. João VI) that was enacted on the 28 April 1809. Later, Brazil joined the Paris Convention in 1883.

Brazil, as a founding member of the Paris Convention granted patents with Constitutional acceptance and protection within the first Imperial Charter of 1824.¹⁸⁰ Nowadays, IP rights find constitutional protection in Article 5 (XXIX) from the *Constituição do República Federativa do Brasil*, as reformed in 1988 (hereinafter the constitution).¹⁸¹ On 1 January 1995 Brazil became a WTO member state and thereafter enacted the IP law N° 9279 (hereinafter IP Code) where rights and obligations relating to industrial property were regulated, including compulsory licences.¹⁸² This legislative reform has allowed the country to comply with the minimum standards of protection settled by the Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS Agreement. Patents for chemical products, foods, pharmaceutical products and processes are

¹⁷⁸ IBGE, 'Publication', Preliminary Results of the Sample 16/11/11, *Tableta 1.1*

<censo2010.ibge.gov.br/en/resultados> accessed 20 November 2012

¹⁷⁹ See, WHO, *Perfil País – Brasil* <www.who.int/countries/bra/en/> accessed 20 November 2012.

Also see, WHO, Global Health Observatory Data Repository, 'Demographic and socioeconomical statics: Population', 2010 <apps.who.int/gho/data/#> accessed 1 December 2012

¹⁸⁰ Boges Barbosa, D., 'The New Brazilian Patent Law', unpublished.

<denisbarbosa.addr.com/papers.htm> accessed 20 November 2012

¹⁸¹ *Constituição do República Federativa do Brasil*, Texto promulgado em 05 de outubro de 1988, D.O. DE 05/10/1988 <apps.who.int/gho/data/#> accessed 20 November 2012, *Also*

see <www.planalto.gov.br/ccivil_03/Constituicao/Constitui%C3%A7ao.htm> accessed 20 November 2012

¹⁸² For further information, See: Section III Article 68 Law No. 9.279 of May 14, 1996. Compulsory Licensing sections of Brazil's Patent Law, translated into English by the WIPO

to be granted as long as the patent claim meets the patentability requirements also settled by law.¹⁸³

The Brazilian government made use of the compulsory licence provision within the IP Code on 4 May 2007 to address a national public health challenge. With Decreto 6.108, published at the DOU on 7.5.2007, the patents to produce and for the product Efavirenz were considered to be of public interest. The Government sanctioned the compulsory licence for the antiretroviral 'Efavirenz' for a period of five years.¹⁸⁴ Once the term expired in 2012, it was deemed necessary to extend the use of the patent via compulsory licence for an additional five years.¹⁸⁵

Scholars have pointed out that the Brazilian patent system should not have been structured in a manner simply to please or fulfil trading partners' or foreign interests, but instead, the Brazilian patent system should be restructured accordingly with Brazilian societal needs.¹⁸⁶ Protecting public health in Brazil seems to be a priority given by the amendment to the IP Code and the creation of the prior consent mechanism to specifically address public health concerns related to patents. In Lei Nº 10196/01 (hereinafter the new IP Code) the Agência Nacional de Vigilância Sanitária-ANVISA was enabled to assess the impact on public health derived from granting a pharmaceutical patent.¹⁸⁷ This mechanism will be further analysed below.

Other scholars have argued in favour of Brazil's consciousness over public health challenges, asserting that the new IP Code aims to protect and promote the development of new technologies that will allow the national industry to develop as well, thus benefiting Brazil's social needs.¹⁸⁸ The rationale behind prompting developing countries to improve their internal legislation with the minimum standards of intellectual property protection is due to the system's contribution to national development. By encouraging the creation of new companies, in theory, these will also benefit from technology transfer while the patent system is also intended to boost the economical development of the given country.

Brazil is currently a Member country of both the World Trade Organization and the Mercado Común del Sur-MERCOSUR. It has ratified several free trade agreements in the context of MERCOSUR, but none of these with major

¹⁸³ Bird, R., and Cahoy, D. R., 'The Emerging BRIC Economies: Lessons from Intellectual Property Negotiation and Enforcement' (2007) 5*Northwestern Journal of Technology and Intellectual Property*3,404

¹⁸⁴ TWN Third World Network, Brazil Sanctions compulsory license on EFAVIRENZ, TWN Info services on Health issues 9 May.2007<www.twncside.org.sg/title2/health.info/twninfohealtho88.htm> accessed 20 November 2012

¹⁸⁵ BRASIL, Presidência da República, Decreto 7.723/2012 from 7 May 2012. Prorroga o Prazo de Vigência do Licenciamento Compulsório, por Interesse Público, das Patentes Referentes ao EFAVIRENZ para fins de uso não commercial, de que trata o DECRETO Nº 6.108, de 4 de Maio de 2007, Brasília-2012.

¹⁸⁶ Borges Barbosa, 'The New Patent Law'.

¹⁸⁷ BRASIL, Presidência da República, Lei nº 10196/01, from February 14th, 2001, Altera e acresce dispositivo à Lei nº 9.279, de 14 de Maio de 1996, que Regula Direitos e Obrigações relativos á Propriedade Industrial, e dá outras providências.

¹⁸⁸ Andrade Capp, D., 'A Função Social Da Propriedade Intelectual' in *Limites Jurídicos da Regulação e Defesa da Concorrência*(Ed. Sergio Antonio Fabris, 2003) at 45

economies.¹⁸⁹ In terms of intellectual property rights, there is no FTA ratified by Brazil that thus far regulates these rights in the same manner as it has been regulated within the TRIPS Agreement; for instance, the Asunción Treaty provides the framework to MERCOSUR, but does not regulate intellectual property rights in a similar manner to other FTAs that settle higher standards of protection.¹⁹⁰ Nevertheless, it is important to highlight that even when patents are not governed within MERCOSUR's frame or subsequent FTAs, it does not mean that IPRs are excluded from the interests of this integration organisation. In terms of intellectual property, MERCOSUR has the following framework Protocolo de Harmonização de Normas Sobre Propriedade Intelectual no Mercosul em Matéria de Marcas, Indicações de Procedência e Denominações de Origem- also known as Protocol of the Harmonization of Intellectual Property Norms; the Protocolo De Armonización De Normas En Materia De Diseños Industriales Mercosur/Cmc/Dec N°16/98; and the Protocolo do Solução de Controvérsias, de obtenções vegetais MERCOSUR/CMC/DEC N°1/99.¹⁹¹

Some have asserted that the commitment to public health and the local industry on behalf of the Government goes beyond commercial relations. Recent negotiations with the Peoples Republic of China, which have led to rumours on a FTA between the nations, backs up the argument in favour of Brazil. Such commercial exchange or negotiations only reached a “global strategic partnership” given their influence on the global economy, but allegedly the Brazilian government is reluctant to raise IP standards of protection via TRIPS plus agreements since this will be detrimental to its local auto industry, among other industries.¹⁹²

Despite efforts towards development, there are social challenges to overcome in Brazil. These are namely prevalent poverty rates, social discomfort in terms of national expenditure due to what is seen as unnecessary expenditure (World Cup 2014), rampant corruption and poor public services that have all caused social turmoil prompting the Government to take action and to take care of the pressing issues.¹⁹³

In terms of public health, public health care in Brazil has not always been what it is today. Before its democratisation, as labelled by scholars, at least 70% of the population was excluded from public health services and access to medicines since the military government at that time “only provided medical curative services for civil servants and urban middle class”.¹⁹⁴

¹⁸⁹ *The Brunei Times*, China ready for Mercosur FTA, Sao Paulo – 28 June 2012. Also See Information on Brasil – Foreign Trade Information System SICE OAS

<www.sice.oas.org/ctyindex/BRZ/BRZagreements_e.asp> accessed 14 March 2014

¹⁹⁰ Morin, J. F., ‘Dancing with Brazil, South Africa, India and China: Large Developing Countries and Bilateralism’ (Unisfera, Canada-2008) *Idées pour le débat: Global Governance* 2, 1-8.

¹⁹¹ Barbosa, Denis, ‘Propriedade Intelectual no âmbito do Mercosul’in *Mercosul’in Usucapião de Patentes e Outros Estudos de Propriedade Industrial* (Lumen Juria Editorial– 2006) 1-857, 3 <www.denisbarbosa.addr.com/arquivos/200/internacional/pimercosul.doc> accessed 14 March 2014

¹⁹² *Reuters*, ‘Brazil, China sign trade agreements’ Arab News, (23 June 2012)

¹⁹³ Marull, Y., ‘Brazil Leader readies reforms to defuse social unrest’, *Fox News*, 01 July 2013, at <www.foxnews.com> accessed 30 July 2013)

¹⁹⁴ Nuun, A., *The Politics of AIDS Treatment in Brazil* (Springer Ed. 2009) at 32

After the military dictatorship Brazil began to re-structure the public health care system. Community pressure played an important role in achieving the health reform as foreseen within the Constitutional amendment of 1988.¹⁹⁵ From the early 1980s, when the first HIV/AIDS cases were reported, 210,254 accumulative HIV/AIDS cases have been counted in the country until 2001.¹⁹⁶ Scholars have suggested that a 'first generation' of Brazilian activists approached the government to bring their attention to the illness making use of a human rights based strategy to raise awareness towards creating a health care system equal for all.¹⁹⁷

This social pressure later on translated into the constitutional amendments of 1988, which integrated access to medicines as part of the right to health. The constitutional approach towards public health will be analysed within the heading below. From the evolution of the public health perspective, after the military government was overthrown, to tackle illnesses such as HIV/AIDS, high blood pressure, asthma and diabetes became among the top priorities for the Brazilian government.¹⁹⁸ For the purpose of this research, when making reference to and analysing the health care system, policies and developments the focus will be on access to medicines and the most important developments in terms of the HIV/AIDS crises.

3.2. Constitutional Approach towards Intellectual Property Rights and Public Health

Intellectual property rights in Brazil were protected long before the Constitution of 1988, as stated above, but this constitutional reform conditioned IP rights to a social function criteria. They received constitutional protection even before the independence of Brazil from Portugal. Thus, expropriating patent rights due to public interest was possible from as early as 1891 by virtue of Articles 72, § 17 to 25 of the Constitution.¹⁹⁹

¹⁹⁵ Galvão, J., 'Brazil Access to HIV/AIDS Drugs: A question of Human Rights and Public Health' (2005) 95 *American Journal of Public Health: Health Policy and Ethics* 7, 1110-1116, at 1112

¹⁹⁶ Galvão, J., 'A política brasileira de distribuição e produção de medicamentos anti-retrovirais: privilégio ou um direito?' (2002) 18 *Cadernos de Saúde Pública* 1, 213-219, at 214

¹⁹⁷ Galvão, J., 'Brazil Access to HIV/AIDS Drugs', 112

¹⁹⁸ Mendes, Amanda, 'Vigitel 2012: 7,4 dos brasileiros têm diabetes' *DOENÇAS CRÔNICAS* (da Agência de Saúde – 14 Nov 2013) <portalsaude.saude.gov.br/index.php/cidadao/principal/agencia-saude/noticias-antiores-agencia-saude/6861> accessed 15 March 2014

¹⁹⁹ Constituição da República do Brasil 1891, "Article 72: The Constitution ensure to Brazilians' and foreigners residing in the country the inviolability of their rights concerning freedom, personal and property security, in the following terms:

§17 - the property right shall be guaranteed to the fullest, except expropriation through previous compensation due public interest; §25- Industrial inventions belonging to their creators will receive a temporary privilege by law or it will be granted by Congress a reasonable prize if its necessary to publish or use the invention." Translation by the author. Original text in Portuguese "Art 72 - A Constituição assegura a brasileiros e a estrangeiros residentes no País a inviolabilidade dos direitos concernentes à liberdade, à segurança individual e à propriedade, nos termos seguintes: § 17 - O direito de propriedade mantém-se em toda a sua plenitude, salva a desapropriação por necessidade ou utilidade pública, mediante indenização prévia. § 25 - Os inventos industriais pertencerão aos

The Brazilian political constitution – Constituição Federativa da República do Brasil, even within the latest amendment in 2010 named ‘Emenda Constitucional N° 64’ from the 4 February of that year, maintains in Article 6 that the right to health is to be considered as a part of the other social rights to be enjoyed by Brazilians.²⁰⁰

Intellectual property rights are found under the umbrella of fundamental rights, specifically in Título II (I) from the Constitution where Dos Direitos e Garantia Fundamentais (Fundamental Rights and Guaranties) are settled. Health rights are also foreseen within the same Title, but after intellectual property rights. This has given grounds for a debate to arise among scholars on whether or not patents should have been drafted in the section for economical rights within the constitution:

Article 5, ... everyone are equal before the law, without distinction whatsoever, guaranteeing to Brazilians and foreigners residing in the country the inviolable right to life, liberty, equality, safety and property, as follows:

XXIX – The law shall ensure temporary privileges for the use of industrial inventions by their authors, as well as the protection of industrial creations, ownership of trademarks, company names and other distinctive signs, taking into consideration the social and technological interests and the country’s economic development.²⁰¹

Together with the debate on IPRs being natural rights, the ‘priority’ given to these over health in the political Constitution became highly contested. Some scholars have argued that intellectual rights are economic rights; also arguing that as immaterial property rights these should have been enclosed within either the property or the economic rights chapter.²⁰² Some other scholars assert that even when IP rights are within the scope of fundamental rights, the difference with fundamental rights per se relies on the fact that the first have a direct and immediate application, whereas the second ones need to be regulated by a legislative tool. The Constitution highlights that “the law shall ensure temporary rights...”, hence, only foreseeing the property right of the invention as a fundamental right entails the creator to obtain protection for their invention, but in any case a legal instrument is necessary to safeguard temporary protection.²⁰³

seus autores, aos quais ficará garantido por lei um privilégio temporário, ou será concedido pelo Congresso um prêmio razoável quando haja conveniência de vulgarizar o invento.”

<www.planalto.gov.br/ccivil_03/constituicao/Constituicao091.htm>accessed 14 September 2014

²⁰⁰ Constituição da República do Brasil de 1988, Artigo 6°, “São direitos sociais a educação, a saúde, a alimentação, o trabalho, a moradia, o lazer, a segurança, a previdência social, a proteção à maternidade e à infância, a assistência aos desamparados, na forma desta Constituição.”

²⁰¹ Constituição da República do Brasil de 1988, Artigo 5°, numeral XXIX: Art. 5° Todos são iguais perante a lei, sem distinção de qualquer natureza, garantindo-se aos brasileiros e aos estrangeiros residentes no País a inviolabilidade do direito à vida, à liberdade, à igualdade, à segurança e à propriedade, nos termos seguintes: XXIX - a lei assegurará aos autores de inventos industriais privilégio temporário para sua utilização, bem como proteção às criações industriais, à propriedade das marcas, aos nomes de empresas e a outros signos distintivos, tendo em vista o interesse social e o desenvolvimento tecnológico e econômico do País;” Original version in Portuguese, translation above by the author and partially taken from Viviane Yumy Mitsuuchi Kunisawa id.

²⁰² Proner, C., *Propriedade Intelectual e Direitos Humanos* (Ed. Sergio Fabris, 2007) at 139

²⁰³ Rocha Furtado, L., *Sistema de Propriedade Industrial no Direito Brasileiro: Comentários à Nova Legislação sobre Marcas e Patentes Lei n° 9.279, de 14 de Maio de 1996* (Ed. Brasília Jurídica, 1996) at 84-86

Whether or not intellectual property rights are given the status of fundamental rights or as safeguards within the constitutional text, the fact is that these rights are “constitutionally protected”, and the country shall ensure adequate legislative mechanisms to enforce their protection.

By arguing about the priority given in Brazil to IPRs, the debate on balancing rights has emerged. In order to balance rights or to establish real priority it seems necessary to question which institution is entitled to balance them. If there is a range of possibilities in giving a solution, then in general terms the parliament should be the body to solve such issues. Balancing means a range of possible solutions, but if there is only a single possible outcome then the institution providing the solution should be a constitutional court; a constitutional court is the only one that can examine and rule over constitutional interpretation issues.

According to some foreign scholars, balancing the right to property and the right to health is very important as to delimitate the scope of intellectual property rights for this matter.²⁰⁴ The trend followed by judges does not seem to be unanimous, however, the Segunda Seção do Superior Tribunal de Justiça from the Superior Tribunal de Justiça in June 2010 ruled over the time of protection for a pipeline patent held by Pfizer for the production and commercialization of Viagra in the country. This case brought certain concerns to the spotlight, mostly due to the interpretation used by the judge who ruled in favour of the nation clarifying the expiration day for the patent within the national territory arguing that this expired at the end of 2010 instead of at the end of 2011 as it would happen in the rest of the world.²⁰⁵ Even when the ruling does not specifically addresses the issue of Constitutional balancing it does portray to a certain extent the position of Brazilian judges when taking into consideration Brazilian health concerns.

Given that the Brazilian Constitution requires a specific legislative tool to provide protection to that temporary right, then attention must be drawn to the intellectual property legislation in Brazil. An analysis of this will follow later in the chapter.

3.2.1. Public Health and Access to Medicines

The right to health rights finds constitutional protection within Articles 6, 196 - 200 of the Constitution, where not only are the rights settled but also terms, scope and the States’ duties to ensure access to public health. In this regard, Article 6 defines health as a social right safeguarded within the scope of fundamental rights.

²⁰⁴ Geiger, C., ‘Fundamental Rights, a Safeguard for the Coherence of Intellectual Property Law?’ (2004) 35 *IIC International Review of Intellectual Property and Competition Law* 3, at 241 – 364

²⁰⁵ BRASIL. Superior Tribunal de Justiça, RECURSO ESPECIAL Nº 731.101-RJ(2005/0036985-3)

Relator: Ministro João Otávio de Noronha, Sessão de 28.04.2010

<www2.stj.jus.br/processo/pesquisa/?src=1.1.2&aplicacao=processos.ea&tipoPesquisa=tipoPesquisaGenerica&num_registro=200500369853> accessed 04 April 2014

According with this Constitution, social rights are education, *health*, nutrition, work, housing, leisure, welfare, motherhood and child protection, assistance for the homeless...²⁰⁶

Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.²⁰⁷

To implement the right to health the Brazilian government enacted Lei nº 8.080/90 and Lei nº 8.142/90²⁰⁸ structuring the universal health care system named Sistema Único de Saúde (hereinafter SUS) based on the principles of universality, equality and full health care coverage.²⁰⁹ The right of access to medicines can be also inferred, as suggested by some scholars, from Lei nº 8.080/90, Article 6.I (d) where pharmaceutical assistance and integral medical care are described as part of SUS duties.²¹⁰ In views of consolidating SUS, thus to ensure access to medicines as part of the fundamental right to health, the Ministry of Health committed to providing AIDS treatment to tackle the HIV/AIDS crisis in response to society's demands, while at the same time it began producing generic ARV drugs in 1993 as well.²¹¹

One of the challenges to controlling HIV/AIDS from spreading in Brazil was related to blood transfusions. Allegedly, 70% of haemophiliacs were infected with the illness. Therefore, controlling quality and safety was paramount in the success in the fight against HIV/AIDS.²¹² Before the Constitutional amendment of 1988, no law or nothing within the existent legislation neither forbade nor controlled the selling of blood.²¹³ Constitutional Article 199, paragraph 4 expressly restricts

²⁰⁶ Emenda Constitucional Nº 64/2010 to the Constituição Federativa da República do Brasil, Article 6 "São direitos sociais a educação, a saúde, a alimentação, o trabalho, a moradia, o lazer, a segurança, a previdência social, a proteção à maternidade e à infância, a assistência aos desamparados, na forma desta Constituição." Original text in Portuguese, translation by the author. <www.planalto.gov.br/ccivil_03/constituicao/Emendas/Emc/emc64.htm#art1> accessed 14 September 2014

²⁰⁷ Article 196, Constituição Federativa da República do Brasil

²⁰⁸ Brasil, Presidência da República, Lei nº 8.142, de 18 de dezembro de 1999, Dispõe sobre a participação da comunidade na gestão do Sistema Único de Saúde (SUS) e sobre as transferências intergovernamentais de recursos financeiros na área da saúde e dá outras providências. Brasília-1999.

²⁰⁹ Brasília, Presidência da República, Lei nº 8.080, de 19 de Setembro de 1990, Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências, Brasília: MDS, 1990. Also see, Elias, P., and Cohn, A., 'Health Reform in Brazil: Lessons to Consider' (2003) 93 *American Journal of Public Health* 1, 44-48

²¹⁰ Lei nº 8.080/90 - Artigo 6: "Estão incluídas ainda no campo de atuação do Sistema Único de Saúde (SUS): I – a execução de ações: d) de assistência terapêutica integral, inclusive farmacêutica;" Translation within the SUS duties is the responsibility of providing medical care and pharmaceutical assistance. Original text in Portuguese <leifederal.wordpress.com/2008/06/19/lei-8080/> accessed 20 May 2010

²¹¹ Nunn, A., Da Fonseca, E., and Gruskin, S., 'Changin global essential medicines norms to improve access to AIDS treatment: Lessons from Brazil' (2009) 4 *Global Public Health* 2, 131-149, 133

²¹² Teixeira, P., 'Universal Access to AIDS medicines: the Brazilian experience' (2003) *Divulgação em Saúde para Debate* 27, 184-195, 186

²¹³ Nuun, A., 'The Politics of AIDS Treatment in Brazil' (Springer Ed, 2009) 42

blood sale mandating to regulate by law these kinds of transactions within a strict framework.²¹⁴ The legislation came later on in 2001 as part of the reforms that reshaped the current health care system.²¹⁵

The first Brazilian drug policy dates from 1964 when the *Relação Básica e Prioritária de Produtos Biológicos e Materiais para uso Farmacêutica Humano e Veterinário* (Basic and Priority List of Biological Products and Material for Human Pharmaceutical and Veterinarian use) was enacted by Decree nº 53.612 on the 26 February 1964. Promoting access to medicines or essential medicines was deemed challenging, as some scholars have pointed out. Strong political influence in selecting and purchasing the medicines contained on the “List” did not correspond to any specific strategy, since the concept of solidarity among politicians was not that relevant when tackling illnesses afflicting Brazilians.²¹⁶ Moreover, the new drug policy in Brazil is the result of massive campaigning towards prioritising public health at the National and Federative level.

Allegedly, access to HIV/AIDS medicines became firmly established in 1996 when free distribution of these medicines was guaranteed by the government via Lei nº 9.313.²¹⁷ This legislation was also known as ‘Sarney’s Law’ due to the sponsorship by the former president José Sarney. In light of the universal and equality principles, free access to HIV/AIDS drugs to treat people living in Brazil with the illness was now provided.²¹⁸

Later on in 1998, the National Drug Policy (Portaria nº 3.916/98 - Política Nacional de Medicamentos) was enacted to complement the National Health Policy. Ensuring safety, quality and efficiency, together with promoting rational use of medicines and access to essential medicines are now the principles settled

²¹⁴ Article 199, Paragraph 4 – “The law shall provide for the conditions and requirements which facilitate the removal of organs, tissues and human substances for the purpose of transplants, research and treatment, as well as the collection, processing and transfusion of blood and its by-products, all kinds of sale being forbidden.” Unofficial translation <pdba.georgetown.edu/constitutions/brazil/english96.html#mozTocId895389> accessed 4 December 2012

²¹⁵ Brasília, Presidência da República, Lei nº 10.205, de 10 de Maio de 2001, Regulamenta o § 40 do art. 199 da Constituição Federal, relativo à coleta, processamento, estocagem, distribuição e aplicação do sangue, seus componentes e derivados, estabelece o ordenamento institucional indispensável à execução adequada dessas atividades, e dá outras providências, Brasília: MDS, 2001.

²¹⁶ Carvalho, P. (ed.) *Patentes farmacêuticas e acesso a medicamentos* (São Paulo: Atlas, 2007) at 21. See also, Steffen Guise, M.; Liang Wang, D. W., and de Campos, T. C., ‘Access to Medicines: Pharmaceutical Patents and the Right to Health’ in Shaver, Lea (ed.) *Access to Knowledge in Brazil: New research on Intellectual Property, Innovation & Development* (Bloomsbury Academic, 2010) 103-117. Also See Nunn, A. (ed.), *The Politics and History of AIDS Treatment in Brazil* (Springer, 2009) 31-44; and Gómez, E., ‘A Temporal Analytical Approach to Decentralization: Lessons from Brazil’s Health Sector’ (February 2008) 33 *Journal of Health Politics, Policy and Law* 1, 53-91

²¹⁷ Galvão, J., ‘Brazil Access to HIV/AIDS Drugs’, 112. According to the same scholar, medicines for malaria, Hansen disease, cholera, hemophilia, diabetes, schistosomiasis, trachoma, leishmaniasis and filariasis were also strategical for the government and therefore purchases by the federal government ensure peoples’ access to them at affordable prices.

²¹⁸ Nunn, A., Da Fonseca, E., and Gruskin, S., ‘Changin global essential medicines norms to improve access to AIDS treatment’, 134

within the National Drug Policy.²¹⁹ This drug policy was aimed at creating and approving the *Relação Nacional de Medicamentos Essenciais* – National List of Essential Medicines (hereinafter RENAME or the list). The first paragraph of this Ministerial regulation recognises the need to provide the country with a proper and well-structured National Drug Policy, as well as to define essential medicines and the role of the institutions involved.²²⁰

RENAME did not seem to have been created without counter arguments; some scholars have suggested that this list of essential medicines is not completely legal given to its restrictive character. Since the list is limited to only those common or most popular diseases affecting the Brazilian population, access to medicines should be granted in general and it should not be restrictive.²²¹ Both the National Drug Policy and a National List of Essential Medicines are key pieces of legislation for each country to settle priorities within the health care system, i.e. access to determined medicines and also treatment.²²²

The evolution of public health in Brazil is closely related to the national programmes developed to treat HIV/AIDS and STDs, and thus far, it has been estimated that by 1998 some 540,000 people were living with AIDS.²²³ The rationale behind addressing access to health towards solving the aforementioned crisis seems to rely on significant expenditure savings for the government. Scholars have highlighted two key arguments in favour of the distribution and continuation of HIV/AIDS treatment. On the one hand, there seems to be a clear effect of antiretroviral treatment in terms of reducing deaths; and on the other, a significant decrease in hospital admissions and treatment costs have reflected up to \$ 1.1 billion in savings for the Ministry of Health.²²⁴

Besides the HIV/AIDS programme, in general the national health care system also provides attention and access to other needed essential medicines. In the light of Chapter III of the Law regulating terms and conditions to promote and protect health, therapeutic assistance and medicines are to be provided in accordance with medical protocols.²²⁵ If there are no protocols available, then medicines and treatment are to be provided according to the guidelines instructed by an official agent from SUS.²²⁶ The duties of the Brazilian health care

²¹⁹ Brasília, Ministério da Saúde, Portaria n° 3.916/GM, de 30 de outubro de 1998, Política Nacional de Medicamentos, Brasília: MDS, 1998. See Introdução, second paragraph. Original text in Portuguese <portal2.saude.gov.br/portal/arquivos/pdf/portaria3916_30out98.pdf> accessed 4 December 2012

²²⁰ Idem

²²¹ Steffen Guise, M.; et al, 'Access to Medicines: Pharmaceutical Patents and the Right to Health' at 106

²²² WHO, Importance of drug policy concept in 'How to Implement National Drug Policies' at 6-10

²²³ Nuun, A., 'The Politics of AIDS Treatment in Brazil' (Springer Ed, 2009) 42

²²⁴ Galvão, J., 'Access to Antiretroviral Drugs in Brazil', *The Lancet*, (November 5, 2002) 1-4, <image.thelancet.com/extras/01art9038web.pdf> accessed 3 December 2012

²²⁵ Brasília, Presidência da República, Lei n° 8.080, de 19 de Setembro de 1990, Dispõe sobre as condições para a promoção, proteção e recuperação da saúde, a organização e o funcionamento dos serviços correspondentes e dá outras providências, Brasília: MDS, 1990. Article 19-M (1)

²²⁶ Brasília, Presidência da República, Lei n° 12.401, de 28 de Abril de 2011, Altera a Lei no 8.080, de 19 de setembro de 1990, para dispor sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde - SUS. Brasília: MDS, 2011

system extend to the distribution of medicines to patients, as long as assistance is sought in public hospitals.²²⁷ Health care services can also be provided by the private health care sector although it is not obliged to grant either free medication or medical care.²²⁸

According to the legislation, Brazilians should have access to essential medicines for free, and if not, at affordable prices. Thus, scholars have brought to the spotlight that access to medicines is correlated not only with affordability but also with availability of medicines.²²⁹ Availability seems to be a topic of great concern in Brazil given that from a total of 71% of essential medicines in the market, the availability of generics during 2009 was below 10%.²³⁰ Nevertheless, these rates grew by 2013, and it is estimated that at least 23,5% of the medicines are available in their generic form.²³¹ When discussing affordability, it has been suggested that prices of medicines within the retail sector are influenced by procurement practices. This indicates that pharmacies that purchase smaller quantities from those purchased by wholesalers are not able to provide cheaper prices due to all the costs involved.²³²

One of the goals of the Brazilian health care model is to provide universal coverage and also to protect people from economical hazards. Therefore the government launched the 'popular pharmacy programme' in 2004 that was to ensure affordability and availability of medicines.²³³ In light of the provisions in the programme, the government subsidised medicines to ensure lower prices also at private pharmacies. According to the legislation, priority must be given to generic versions both for treatment and prescriptions.²³⁴ Regardless of legislative efforts, the popular pharmacies managed by the public sector portray lower availability of medicines than the ones privately managed.²³⁵

²²⁷ Brasília, Presidência da República, Lei nº 8.080, Article 4§1

²²⁸ Brasília, Presidência da República, Lei nº 8.080, Article 4§2. Also see, Article 43 where public health shall be free except for private providers whom are allow to charge for their services

²²⁹ Bertoli, A., et al. 'Is the Brazilian pharmaceutical policy ensuring population access to essential medicines?' (BioMed Central, April-2011) 8 *Globalization and Health* 6, 1-10

²³⁰ Silva Miranda, E., et al. 'Disponibilidade no setor público e preços no setor privado: um perfil de medicamentos genéricos em diferentes regiões do Brasil' (2009) 25 *Cadernos de Saúde Pública* 10, 2147-2158

²³¹ 'Mercado de remédios genéricos cresce 16% no 1º semestre' G1 Economia-em São Paulo, 24 July 2013 </g1.globo.com/economia/noticia/2013/07/mercado-de-remedios-genericos-cresce-16-no-1- semestre.html> accessed 15 March 2014

²³² Bertoli, A., et al. 'Is the Brazilian pharmaceutical policy ensuring population access to essential medicines?' at 2

²³³ Brasil, Ministério da Saúde, Decreto nº 5.090, de 20 de Maio de 2004, Regulamenta a Lei no 10.858, de 13 de abril de 2004, e institui o programa "Farmácia Popular do Brasil", e dá outras providências, Brasília:MDS, 2004<portal.saude.gov.br/portal/arquivos/pdf/decreto5090.pdf> accessed 4 December 2012 and also See Brasil, Ministério da Saúde, Portaria nº 971, de 15 de Maio de 2012, Dispõe sobre o Programa Farmácia Popular do Brasil, Brasília:MDS, 2012<portal.saude.gov.br/portal/arquivos/pdf/portaria_971.pdf>accessed 4 December 2012

²³⁴ See, Brasília, Ministério da Saúde, Portaria nº 3.916/GM, de 30 de outubro de 1998, Política Nacional de Medicamentos, Brasília:MDS, 1998

²³⁵ Du Bocage Santos Pinto, C., et al., 'Medicine prices and availability in the Brazilian Popular Pharmacy Program' (2010) 44 *Revista da Saúde Pública* 4, 1-8, 5

Despite scholars arguing against the availability of generic medicines in Brazil,²³⁶ recent studies have shown that both delays and difficulties to access health care provided within the public health care system are by far the more pressing things to solve when seeking access than the availability of medicines in one or the other sector.²³⁷ Accordingly, 61% of the population gave negative remarks when asked about access to public health care providers. Of those interviewed, some 55% regarded delays and difficulties in receiving health care attention as among the main issues challenging the public health care providers, and just 4% regarded the lack of medicines as an issue.²³⁸ In this respect, the role of judges in improving health care policies has been acknowledged, on the one hand, since they have often ruled in favour of Brazilians by addressing access to health as a mandate from the Constitution;²³⁹ but on the other hand, the challenge in obtaining such decisions has been pointed out given that only those with a certain level of understanding about their rights and legislation are able to seek legal advice in claiming their right to health before a judge.²⁴⁰

In order to improve health care services, scholars also argue for the need to assess the issue from two different perspectives. From the Constitution's point of view, health challenges can be solved from an idealistic standpoint; whereas when foreseeing a solution from the illness point of view, social, economical and cultural implications will be taken into consideration. Therefore, it is said that the ideal health care system is one that provides scheduled and preventive medicine, and in its higher level this shall integrate preventive and incidental, physical and psychological health care.²⁴¹ Some have even argued in favour of health care development as a consequence of technical and scientific developments at a national level.

Another important player to take into consideration is the National Health Institute (Agência Nacional de Vigilância Sanitária (hereinafter ANVISA) created in the National Drug Policy. This is an independent regulatory agency under the Health Ministry created in 1999 to protect public health by ensuring quality, efficiency and safety of those products and processes subject to sanitary control.²⁴² Among ANVISA's competences, is to determine whether or not a

²³⁶ Damasco Bertoli, A., et al. 'Is the Brazilian pharmaceutical policy ensuring population access to essential medicines?', and also See, Jane Galvão, 'A política brasileira de distribuição e produção de medicamentos'.

²³⁷ Pesquisa CNO-IBOPE: retratos da sociedade brasileira: saúde pública – (janeiro 2012) – Brasília: CNI, 2012, 18-29, 29
<arquivos.portaldaindustria.com.br/app/conteudo_24/2012/07/09/76/20120828014744353629a.pdf> accessed 14 March 2014

²³⁸ Idem. For precise information about the main challenges pointed out by the survey refer to the graphic on page 29

²³⁹ Galvão, J., 'Brazil Access to HIV/AIDS Drugs', 112.

²⁴⁰ Vargas Terrazas, Fernanda, 'O Poder Judiciário como voz institucional dos pobres: o caso das demandas judiciais de medicamentos' 253 *Revista de Direito Administrativo* (2010) 79-115, 111

²⁴¹ Luciane de Carvalho, P., 'Patentes farmacêuticas e acesso a medicamentos' (Ed. Atlas, 2007) 1-216, 18

²⁴² Brasil, Ministério da Saúde, Lei nº 9.782, de 26 de Janeiro 1999, Define o Sistema Nacional de Vigilância Sanitária, cria a Agência Nacional de Vigilância Sanitária, e dá outras providências. Brasília:MDS, 1999. Art. 6º "A Agência terá por finalidade institucional promover a proteção da saúde da população, por intermédio do controle sanitário da produção e da comercialização de produtos e serviços submetidos à vigilância sanitária, inclusive dos ambientes, dos processos, dos

pharmaceutical product meets with the necessary requirements to obtain a marketing approval.²⁴³ It must be highlighted that marketing approvals are –a regulatory requirement - needed before any pharmaceutical product can be commercialised within the market since these ensure the safety of the product.

In 2001 Brazil implemented a mechanism known as Anuência Previa or Prior Consent aiming to protect public health –this mechanism has nothing to do with marketing approvals even when it is ANVISA the institution granting both. This mechanism has created a dilemma since it grants, or initially granted, a veto power over patents to a different institution than the patent office *per se*. Prior consent will be analysed in detail in the heading below.

3.2.2. Implementing Policies to Ensure Access To Medicines

Brazil has been praised for its efforts in tackling HIV/AIDS –among other illnesses- through the implementation of the National Drug Policy; this policy foresees the use of generics and public procurement as two key elements that address both availability and affordability.²⁴⁴ The José Serra law (as is also known the health reform of 1998 in Portaria nº 3.916/98) in principle decentralised the procurement and distribution of the essential medicines in RENAME. However, the same legislation reserves the right to centralise procurement and distribution of certain medicines for illnesses whose magnitude has severe repercussions for the country's public health context.²⁴⁵ In this respect, the legislation establishes the need to survey, assist and guide i.e. procurement processes to achieve the legislation's mandate to obtain lower medicine prices to increase the population's access to affordable medicines.²⁴⁶ This legislation has been suggested to be the most important health reform implemented addressing the National AIDS Programme, since its objective involved scaling up generic production in Brasil by

insumos e das tecnologias a eles relacionados, bem como o controle de portos, aeroportos e de fronteiras.”

²⁴³ According to Art. 8 §1(1), it is the Agency's competence to regulate and control products or processes which may endanger or have an impact on health, i.e. medicines.

²⁴⁴ Nunn, A. 'The Politics and History of AIDS' at 108

²⁴⁵ Brasília, Ministerio da Saúde – Secretaria de Políticas de Saúde, Departamento de Formulação de Políticas de Saúde, Portaria nº 3.916/GM em 30 de outubro de 1998, Política Nacional de Medicamentos. Artigo 3.3 " A assistência farmacêutica no SUS, por outro lado, englobará as atividades de seleção, programação, aquisição, armazenamento e distribuição, controle da qualidade e utilização - nesta compreendida a prescrição e a dispensação - , o que deverá favorecer a permanente disponibilidade dos produtos segundo as necessidades da população, identificadas com base em critérios epidemiológicos.

No tocante aos agravos e doenças cuja transcendência, magnitude e ou vulnerabilidade tenham repercussão na saúde pública, buscar-se-á a contínua atualização e padronização de protocolos de intervenção terapêutica e dos respectivos esquemas de tratamento.

Assim, o processo de descentralização em curso contemplará a padronização dos produtos, o planejamento adequado e oportuno e a redefinição das atribuições das três instâncias de gestão. Essas responsabilidades ficam, dessa forma, inseridas na ação governamental, o que deverá assegurar o acesso da população a esses produtos. Para o Ministério da Saúde, a premissa básica será a descentralização da aquisição e distribuição de medicamentos essenciais”

²⁴⁶ Idem Artigo 3.3 (d) "no desenvolvimento de iniciativas que possibilitem a redução nos preços dos produtos, viabilizando, inclusive, o acesso da população aos produtos no âmbito do setor privado.”

means of a centralised public strategy to supply generic antiretrovirals both under and without patent protection.²⁴⁷

The ambition and race to scale up production of generics and to achieve lower prices for antiretroviral seems to be motivated by Lei n° 9.313/96 that made it mandatory for SUS to provide all HIV/AIDS patients with free access to medicines necessary for their treatment.²⁴⁸ Given that patent protection was being implemented in Brazil, thus some of the antiretroviral previously manufactured would now fall under patent protection, the country had to find a way to compel the pharmaceutical industry to keep supplying the medicines needed at low prices, and one way to achieve it was via compulsory licences.²⁴⁹ Even when the legislation favoured generics, the Brazilian government became concerned over the quality of generics given amid manufacturing restrictions deriving from TRIPS.²⁵⁰ In 1999 Lei n° 9.787 was enacted that mandated that all generics purchased through public procurement had to be registered by ANVISA after providing quality tests, and satisfying bioequivalence and disponibility criterion as well.²⁵¹

Although SUS provides access to free medication, it has been pointed out that in some cases and given the decentralisation of the public procurement there are actual limitations or medicine shortages impeding patients from receiving free medicines, even when medical attention has been sought at public health care providers. Therefore, patients need to pay full price out of their pocket in the private market unless the medicines are purchased in popular pharmacies where the Government subsidises 90% of the full price while the remaining 10% is covered by the patient.²⁵² Nonetheless, studies have shown that patients have actually managed to continue their treatment thanks to the availability of the medicines within the popular pharmacies programme despite citizens having to pay for treatment themselves.²⁵³

Brazil has been particularly successful in battling HIV/AIDS.H. Hence, to ensure the programme's sustainability and continued improvement, the Brazilian Government has implemented a strategy focusing on three elements: (a) "building on the capacity of social movements to strengthen prevention (early

²⁴⁷ Nunn, A. 'The Politics and History of AIDS' at 111-112

²⁴⁸ Brasília, Presidência da República, Lei n° 9.313 de 13 de Novembro de 1996, Dispõe sobre a distribuição gratuita de medicamentos aos portadores do HIV e doentes de AIDS. Artigo 1° "Os portadores do HIV (vírus da imunodeficiência humana) e doentes de AIDS (Síndrome da Imunodeficiência Adquirida) receberão, gratuitamente, do Sistema Único de Saúde, toda a medicação necessária a seu tratamento."

²⁴⁹ Steffen Guise, M.; et al, 'Access to Medicines: Pharmaceutical Patents and the Right to Health' at 119-121

²⁵⁰ Nunn, A. 'The Politics and History of AIDS' at 119

²⁵¹ Brasília, Presidência da República, Lei n° 9.787 de 10 de Fevereiro de 1999, Altera a Lei no 6.360, de 23 de setembro de 1976, que dispõe sobre a vigilância sanitária, estabelece o medicamento genérico, dispõe sobre a utilização de nomes genéricos em produtos farmacêuticos e dá outras providências.

²⁵² Bertoldi, A., Helfer, A. P., Camargo, A.L., Tavares, A., and Kanavos, P. 'Medicine prices, availability and affordability in Southern Brazil: a study of public and private facilities' *LSE Health Working Paper No. 18/2010*, 1-24, 6

²⁵³ Steffen Guise, M.; et al, 'Access to Medicines: Pharmaceutical Patents and the Right to Health' at 125

detection of HIV-positive) and to enhance patients compliance with protocols; (b) promoting the use of multi-source/generics and the public production of antiretroviral; and (c) including good surveillance and well-coordinated system of care that ensures access to appropriate diagnostic and treatment.”²⁵⁴

The first element of the strategy seems to emphasise the need to prevent the disease via education programmes. Although the surveillance, treatment of opportunistic infections and the development of partnerships between the government and the civil society are also part of this element of the strategy, the mobilisation of the civil society and the work of activists has been key in achieving a wider reach of people in terms of the illness.²⁵⁵ The second element of the strategy entails the development of the Brazilian pharmaceutical industry as to ensure the sustainability of the programme. In previous years all purchases were centralised by the Central Medicine Agency (CEME); however, after implementing the Drug Policy this was decommissioned and all public procurement was to be carried out by the Ministry of Health²⁵⁶ whom invited those interested for a competitive tender to according to the procedures established within Federal Procurement Law.²⁵⁷ And the third element has to do with surveillance and coordinating health care practices that ensure access to both diagnostic and treatment services.²⁵⁸

The Câmara de Regulação do Mercado de Medicamentos (CMED) was created by Decreto nº 4.766 on 26 June 2003 to promote the availability of medicines and to regulate to a certain extent the prices of medicines by allowing manufacturers to adjust prices according to an index fixed in three bands, which at the same time relates to the level of competition based on the market share of generics.²⁵⁹ The idea behind mass scale purchases is to increase the availability and affordability of medicines by promoting competition among the local pharmaceutical sector as well, thus, the use or threat to use compulsory licences is said to have increased the government’s bargaining power to reduce medicines’ prices.²⁶⁰ Allegedly, the Brazilian government was able to drop the yearly cost of antiretroviral treatment from \$4860 per person in 1997 to \$1000 (US dollars) per person in 2001.²⁶¹ With these price reductions the government managed to save approximately \$1.2 billion (US dollars) on AIDS treatment costs.²⁶²

²⁵⁴ Homedes, N., and Ugalde, A., ‘Improving access to pharmaceuticals in Brazil and Argentina’ (March 2006) 21 *Health Policy and Planning* 2, 123-131, 124

²⁵⁵ Ibid at 124

²⁵⁶ Ibid at 124-125. Also see Bermudez, J. et al ‘Expanding access to essential medicines in Brazil’ at 129-130

²⁵⁷ Brasília, Presidência da República, Lei nº 8.666 de 21 de Junho de 1993, Regulamenta o art. 37, inciso XXI, da Constituição Federal, institui normas para licitações e contratos da Administração Pública e dá outras providências.

²⁵⁸ Homedes, N., et al, ‘Improving access to pharmaceuticals in Brazil and Argentina’, 125

²⁵⁹ Bertoldi, A.D, et al. ‘Is the Brazilian Pharmaceutical policy ensuring population access to essential medicines?’ at 7-8

²⁶⁰ Homedes, N., et al, ‘Improving access to pharmaceuticals in Brazil and Argentina’, 125

²⁶¹ Ibid

²⁶² Nunn, A., Massard da Fonseca, E., Bastos, F., and Gruskin, S., ‘AIDS Treatment In Brazil: Impacts And Challenges’ (2009) 28 *Health Affairs* 4, 1103-1113, 1107

Public procurement can ... be a powerful driver of sustainability, by providing incentives for investment, innovation, and scaling of sustainable enterprises, goods, services, and infrastructure across the public and private sectors.²⁶³

By 2004, 7 of the 18-commercially available antiretroviral were produced by local manufacturers, which represent approximately 50% of the ARVs used to treat the illness.²⁶⁴ Due to the price reductions of nearly 78% on average, the Ministry of Health highlighted that by 2001 HIV/AIDS deaths had reduced to between 48-49%.²⁶⁵ The Brazilian government, in order to fulfil the goal of providing universal health coverage for the treatment of HIV/AIDS, had to indebt itself to several donors and had to allocate local resources to finance the aforementioned programme. For instance, Brazil's determination in battling the disease has been pointed out, given that despite the World Bank's restrictions on using borrowed money on drugs to treat the disease, Brazil moved forward in implementing the programme, including investing in infrastructure and human resources development.²⁶⁶ All of these actions are said to have inspired or contributed to the development of similar programmes in developing countries.

Regardless of the improvements, certain challenges remain to be solved; for instance, the periodic revision and expansion of the list of essential medicines are key for Brazil to ensure the realisation of the universal coverage of all medicines provided by SUS.²⁶⁷ Given Brazil's commitment to protecting both public health and international trading partners, it is necessary to analyse the intellectual property regime to understand how it works and how Brazil has benefited from TRIPS.

3.3. Intellectual Property Rights in Brazil – a Focus on the Pharmaceutical Patents System

The Brazilian doctrine provides several different theories to justify intellectual property rights. One theory focuses on natural rights, arguing that everyone is entitled to his or her own ideas, whilst another theory focuses on the need to compensate the innovator and the inventors for their contribution to society.²⁶⁸

Regarding natural rights, Thomas Jefferson discussed the issue in a letter addressed to Isaac McPherson during 1813, highlighting that there is no such thing as intellectual property rights being natural rights. He strongly argued the fact that fundamental rights are natural rights embedded in the human being,

²⁶³ Dietrich Brauch, M. 'Sustainable Public Procurement in the Sao Paulo State Government: An in-depth case study' TKN Report 2012, The International Institute for Sustainable Development Published by the International Institute for Sustainable Development, 1 <www.iisd.org/pdf/2012/spp_sao_paulo.pdf> accessed 18 March 2014

²⁶⁴ Bacon, O., Pecoraro, M.L., Galvão, J.. and Page-Shafer, K., 'HIV/AIDS in Brazil' (2004) Country Project series (AIDS Policy Research Center, University of California San Francisco – 2004) 1-73, 54

²⁶⁵ see Bermudez, J. et al 'Expanding access to essential medicines in Brazil' at 144-145

²⁶⁶ Nunn, A., et al., 'AIDS Treatment In Brazil: Impacts And Challenges', 1106

²⁶⁷ Bertoldi, A.D, et al. 'Is the Brazilian Pharmaceutical policy ensuring population access to essential medicines?' at 8

²⁶⁸ Andrade Capp, D., 'A Propriedade Intelectual Na Constituição', *Límites Jurídicos da Regulação e Defesa da Concorrência* (Eds. Sergio Fabris: Porto Alegre, 2003) at 52

and the constitutional framework is there to protect human dignity.²⁶⁹ Thus, temporary property rights given to an inventor are nothing else but a gift from social law.²⁷⁰

Despite justifying intellectual property rights according to one or the other theory, these are regulated by a specific legal framework. Therefore, it is important to analyse the constitutional approach toward IPRs in Brazil as reflected within the national law, and other relevant international treaties ratified by the country, especially since the constitution requires IPRs to fulfil with the social function requirement, as will be analysed below.

3.3.1. Current Intellectual Property Framework: Lei nº 9.279

The Instituto Nacional da Propriedade Industrial – National Institute for Intellectual Property (hereinafter INPI or patent office) is a federal agency attached to the Ministério do Desenvolvimento, Indústria e Comércio Exterior – Ministry of Development, Industry and Foreign Trade, and was created on 11 December 1970 by Lei nº 5.648.²⁷¹ INPI is responsible for processing, disseminating and managing intellectual property rights in Brazil.²⁷²

Trade marks registration, patent grants, evaluation of technology transfer contracts and franchising businesses', and also registering computer software,²⁷³ industrial design and geographical indications are among the competences given by law to the patent office.²⁷⁴

Without prejudice of other attributions that could be assigned to INPI, it can also implement measures aiming to accelerate and regulate technology transfer, and to establish mechanisms to improve negotiating conditions, patent grants as well as advising on the need or desirability in ratifying or denouncing conventions, treaties and agreements related to intellectual property rights. The patent office is also to promote extra judicial measures to enforce intellectual property rights in case of infringements.²⁷⁵

²⁶⁹ Borges Barbosa, D., *Uma Introdução à Propriedade Intelectual*, (2da Edição, 2003) 87 - 93

²⁷⁰ Thomas Jefferson in a Letter to Isaac MacPherson in 1813, Koch, A. Peden, W, *The Life and Selected Writings of Thomas Jefferson*. Modern Library, (New York -1972) 629.
<ia331336.us.archive.org/o/items/lifeandselectedw031716mbp/lifeandselectedw031716mbp.pdf> accessed 14 September 2013

²⁷¹ Brasil, Presidência da República, Lei nº 5.648, de 11 de Dezembro de 1970, Cria o Instituto Nacional da Propriedade Industrial e dá outras providências, Brasília:MIC, 1970.

²⁷² See INPI, 'Conheça o INPI'

<www.inpi.gov.br/index.php?option=com_content&view=article&id=1389&Itemid=252> accessed 12 September 2012

²⁷³ See, Lei de Software nº 9.069/98

²⁷⁴ For further insight about the INPI's history see O Instituto, original text in Portuguese
<www.inpi.gov.br/menu-esquerdo/instituto> accessed 14 September 2013

²⁷⁵ Article 240 from the Lei nº 2.729/96 modified Article 2 from Lei nº 5648 as follows: "... INPI's aim will be to enforce, within the national frame, those legislations that regulate industrial property, having in regard its social, economical, legal and technical functions, and it will also stress the desirability, ratification or denouncement from treaties, conventions and agreements about intellectual property rights" Original text in Portuguese, "Artigo 2: O INPI tem por finalidade

The national framework governing intellectual property rights in Brazil comprises the Brazilian Constitution, the Lei nº 9.279 (IP Code), the Lei nº 10.196 (new IP Code) and other internal Resolutions. The international framework shaping the system consists of the Patent Cooperation Treaty, TRIPS Agreement and Paris Convention.

Both the IP Code and the new IP Code brought a series of challenges, namely the working requirement, the pipeline provision and the *anuência prévia* (prior consent) that in some cases may constitute steps to comply with or to take into consideration before patent protection can be granted e.g. pharmaceutical patents. However, before addressing the aforementioned challenges, it is important to analyse further the formalities required to comply with patent procedures in Brazil.

The standards of protection settled by the Agreement on Trade Related Aspects on Intellectual Property Rights were integrated into the domestic law in 1996 and enforced in 1997, however, this was done without making full use of the provisional time given to developing and least-developed nations to make adequate their internal legislation, hence to comply with the minimum standards of protection.

By raising the standards of protection, the term of protection in itself also lengthened. The 1971 IP law (old IP Code) granted 15 years of protection to patents and the IP Code extended the term of protection to 20 years as mandated in Article 33- TRIPS. Since Brazil had no, or a very short transitional period, between the IP and its reform, the aforementioned five years became challenging given that there were patent applications left in the pipeline. Hence, settling the time of protection for a patent claim caught within the transition seemed to be more complicated than originally envisaged.

Scholars suggested that the issue beyond extending the term of protection related to the retroactivity applied in many cases, and sought by right holders whom had filed patent claims TRIPS and the statutory reform, which was less favourable than the new one. Article 33 TRIPS and note 8,²⁷⁶ highlight that the term of protection shall be for 20 years from the filing date and note 8 establishes that in cases where 20 years of protection were not granted then the new term shall be computed from the filing date in the previous system. Depending on the interpretation given to the norm meant that a period of five extra years as a period of grace was given to right holders to keep exploiting the patent. Precisely this point is deemed controversial and unconstitutional according to Article 5°

principal executar, no âmbito nacional, as normas que regulam a propriedade industrial, tendo em vista a sua função social, econômica, jurídica e técnica, bem como pronunciar-se quanto à conveniência de assinatura, ratificação e denúncia de convenções, tratados, convênios e acordos sobre propriedade industrial.” <www.planalto.gov.br/ccivil_03/Leis/L9279.htm> accessed 14 September 2013

²⁷⁶ TRIPS - Article 33: The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date. Note 8: It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant

part XXIX of the 1988 constitution. It has been pointed out that, in theory, an already granted patent could not be extended.²⁷⁷

In general terms the patent system sought to promote constant technology innovation by promoting free competition and inviting companies to invest in obtaining new products as an attempt to accelerate the country's development.²⁷⁸ Therefore, an invention that meets with the patentability requirements settled within Article 8 - Lei nº 9.279 should obtain patent protection.²⁷⁹ The Brazilian IP code does not define what inventions means or is by profiting a definition *per se*, but on the other hand, and in the case of utility model, these have been delimited as "practical objects, or part of it, susceptible to industrial application that also presents a new form or disposition implied within the innovation, and that results in either functional or production improvement."²⁸⁰

Patentability prohibitions within the IP Code are found in Article 10, which at the same time provides a frame or defines what an invention is by enunciating the things that cannot be considered inventions or utility models; thus restrictions related to methods are settled in part (VIII). Techniques, surgical methods or therapeutic methods to treat either humans or animals are excluded from obtaining patent protection despite meeting with the patentability requirements.²⁸¹

The legislation is structured in a manner that instead of establishing prohibitions on a field-by-field basis does it in a more general or vague manner to avoid branching the prohibition of discrimination settled within Article 27 from the TRIPS Agreement. Nevertheless, scholars have contested the recent protection granted to inventions that originally could not be awarded with patent protection or that were expressly excluded from patent protection. However, since these inventions comprise of products and processes related to the chemical sector, the pharmaceutical industry and also biotechnology caught within the transition then patent protection was granted accordingly with the new standards of protection.²⁸²

In accordance with the IP Code inventions, contrary to moral, public order or public health reasons, substances, materials and compositions resulting from modifications of their atomic nucleus and all or part of living organisms (except

²⁷⁷ Borges Barbosa, D., *Usucapião de Patentes e Outros Estudos de Propriedade Industrial* (ed. Lumen Juris, 2006)122

²⁷⁸ Andrade Capp, D., 'A Função Social Da Propriedade Intelectual', 57

²⁷⁹ Brasil, Presidência da República, Lei nº 9.279, de 14 de Maio de 1996, Regula direitos e obrigações relativos à propriedade industrial. Brasília: República, 1996. 'Art. 8º É patenteável a invenção que atenda aos requisitos de novidade, atividade inventiva e aplicação industrial'

²⁸⁰ Article 9 from Lei nº 9.279 "...el objeto de uso práctico, o parte de este, susceptible de aplicación industrial, que presente nueva forma o disposición, implicando acto inventivo, que resulte en mejoría funcional en su uso o en su fabricación."

²⁸¹ Article 10 (VIII) from Lei nº 9.279 provides as none patentable subject matters the following: surgery techniques and methods and therapeutic or methods of diagnosis applied to humans or animals. This prohibition seems to be supported by Article 27 (3) of the TRIPS Agreement.

²⁸² Rocha Furtado, L., *Sistema de Propriedade Industrial no Direito Brasileiro: Comentários á Noca Legislação sobre Marcas e Patentes Lei nº 9.279, de 14 de Maio de 1996*, (1ra Edição, Ed. Brasília Jurídica, 1996) at 45

those trans-generic microorganisms) despite meeting with patentability requirements, shall remain excluded by law from patent protection.²⁸³

Patent ownership in case of several applicants is determined according with the principle '*first to file*'. On the one hand, Article 6º from the IP Code foresees the rules to claiming ownership over an invention, but on the other hand it is in Article 7º where the principle is formally settled. The legislator addresses the possibility of several inventors working separately on the same invention and later on claiming patent rights in different periods of time. To solve this possible scenario, the legislator decided to grant patent rights to the inventor who filed the application first or the one with the oldest application in chronological terms.²⁸⁴

The aforementioned principle leads to examining the priority rights *per se*, in case of foreign inventors looking forwards to protecting their inventions within the Brazilian territory. Brazil as a signatory of the Paris Convention, acknowledges within Article 16º of the IP Code that patent claims vindicating foreign patent rights produce a 'national deposit' effect.²⁸⁵ The practical implication of such applications could translate to receiving preferential treatment, once the patent office receives the application; these have priority even over national claims that might have been presented before the international one.²⁸⁶

However, some preconditions apply so as to recognise priority rights. Firstly, the application has to be made before another member according with the provisions dealing with priority issues within the member countries involved in such an application, for instance the Paris Convention; and secondly, this claim can only be applied for within a period of twelve (12) months from the filing date in the originating country.²⁸⁷

Other scholars have highlighted that the priority right is not a right to a national patent, but it only indicates the value of the application before the Brazilian Government in terms of patentability. Nevertheless, despite having priority rights, these could be challenged either because of specific Brazilian procedural law issues, or because the novelty requirement is not fulfilled.²⁸⁸ Once a patent application has been submitted, the patent office (INPI) will postpone its publication for a period of 18 months so as to prevent it from falling within the public domain,²⁸⁹ unless the applicant requests for an early publication.²⁹⁰ According with one part of the doctrine, when a patent application is published the inventor satisfies the social function requirement, since the information will now be accessible to everyone.²⁹¹ Therefore, it is the administration's duty to protect the application from public display in this 'period of silence' or otherwise

²⁸³ Lei nº 9.279. "Art. 18. Não são patenteáveis..."

²⁸⁴ See Article 7º Lei nº 9.279

²⁸⁵ Article 16º Lei nº 9.279

²⁸⁶ Rocha Furtado, L., 'Sistema de Propriedade Industrial no Direito Brasileiro' at 48

²⁸⁷ Article 17 from Lei nº 9.279. Article 16 §2. Provides the requirements to verify the foreign claim authenticity as to grant priority rights

²⁸⁸ Borges Barbosa, D., *Uma Introdução À Propriedade Intelectual* (2da Edição, Lumen Juris: Rio de Janeiro, 2003) at 294

²⁸⁹ Article 30 from Lei nº 9.279

²⁹⁰ Article 30 §1 from Lei nº 9.279

²⁹¹ Borges Barbosa, D., *Uma Introdução À Propriedade Intelectual*, at 338-339

compensation for damages incurred due to disclosure can be claimed.²⁹² Nevertheless, in certain circumstances INPI will not make public patent applications even after the period of silence passes; that is applications originating in Brazil, the object of which are of interest to national defence.²⁹³

The Brazilian patent procedure is with preliminary examination, and after having verified formal requirements the applicant or interested third party needs to petition within thirty-six (36) months for INPI to perform the substantive examination.²⁹⁴ If there is no petition to examine the content of the patent claim within that timeframe, counted from the filing date, the patent claim will be dismissed and archived.

With the effective start of the examination procedure both the applicant and the interested third party have sixty- (60) days from the publication of the examination request to present the authorities with the documents settled within Article 34 of Lei n° 9.279.²⁹⁵ After this period, if the application has not been shelved, then the administration will publish the decision denying or granting patent rights.²⁹⁶

Beyond the formalities in the Brazilian IP Code, compulsory licences are foreseen within Article 68 §1° (I) for cases where the local working requirement has not been fulfilled. Therefore, if it has taken more than 3 years from the day it was granted,²⁹⁷ then a compulsory licence could be sanctioned to satisfy the internal

²⁹² Article 44 §1 from Lei n° 9.279

²⁹³ Article 75 from Lei n° 9.279 “A patent application originated in Brazil the object of which is of interest to national defence will be processed in secrecy and will not be subject to the publications provided for in this law.

§ 1 - INPI will send the application immediately to the competent organ of the Executive Authorities for the purpose of providing, within 60 (sixty) days, an opinion regarding secrecy. After such a period has passed without any opinion by the competent organ, the application will be processed normally.

§ 2 - Excepting express authorisation by the competent organ, the filing abroad of a patent application the subject matter of which is considered to be of interest to national defence, as well as any disclosure thereof, is prohibited.

§ 3 - The exploitation and the assignment of an application or patent of interest to national defence are conditioned to prior authorisation by the competent organ, with due compensation being guaranteed whenever this implies a restriction to the rights of the applicant or patentee.”

²⁹⁴ Article 33 from Lei n° 9.279

²⁹⁵ Articles 34 from Lei n° 9.279 “Once examination has been requested and whenever so requested, the following should be filed within 60 (sixty) days, on pain of shelving of the application:

I - objections, prior art searches and the results of examination for the grant of corresponding applications in other countries, when there is a priority claim;

II - documents necessary to regularise the proceedings and examination of the application; and

III - a simple translation of the suitable document mentioned in § 2 of article 16, should it have been substituted by the declaration provided for in § 5 of that same article.”

²⁹⁶ See Article 37 from Lei n° 9.279 “Once examination is concluded, a decision will be issued, allowing or rejecting the patent application.”

²⁹⁷ Article 68 §5 from Lei n° 9.279 provides that a compulsory licence due unfulfillment of the local working requirement can be only requested after a period of three (3) years elapses from the date the patent was granted. For other cases different rules apply, and no specific timeframe seems necessary.

market, unless the right holder is able to justify the rationale for not working the patent within the given timeframe.

Article 68 § 1 the following cases shall be also object to compulsory licensing:

I - not to exploit the object of the patent in Brazilian territory or failure to manufacture or incomplete manufacture of the product, or even non-use of a patented process, except in cases not economically feasible, when importation will be admitted, or

II - the marketing that does not meet the needs of the market.

§5° the compulsory licence in § 1° shall be only requested after a period of 3 (three) years from the day the patent was granted”²⁹⁸

Since the legislation gives a three-year timeframe to work the patent, some scholars have argued against it and even suggested its illegality. But both Article 27 of TRIPS²⁹⁹ and Article 5 of the Paris Convention foresee compulsory licences to correct abusive practices. The Convention itself establishes that, “Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.”³⁰⁰

Article 68 “§ 1 - The following may also result in a compulsory licence:

I - the non-exploitation of the subject matter of the patent on the territory of Brazil, by lack of manufacture or incomplete manufacture of the product or, furthermore, by lack of complete use of a patented process, except in the case of non-exploitation due to economic in viability, when importation will be admitted...

²⁹⁸ Lei nº 9.279/96, Article 68: A patentee will be subject to have his patent licensed compulsorily if he exercises the rights resulting therefrom in an abusive manner or by means of it practices abuse of economic power that is proven under the terms of the law by an administrative or court decision: § 1° the following cases shall be also object of compulsory licensing: I - not to exploit the object of the patent on Brazilian territory for failure to manufacture or incomplete manufacture of the product, or even non-use of a patented process, except in cases not economically feasible, when importation will be admitted, or II - the marketing that does not meet the needs of the market. §5° the compulsory licence in § 1° shall only be requested after a period of 3 (three) years from the day the patent was granted” Translation by the author, Original text in Portuguese: “Art. 68. O titular ficará sujeito a ter a patente licenciada compulsoriamente se exercer os direitos dela decorrentes de forma abusiva, ou por meio dela praticar abuso de poder econômico, comprovado nos termos da lei, por decisão administrativa ou judicial. § 1° Ensejam, igualmente, licença compulsória: I - a não exploração do objeto da patente no território brasileiro por falta de fabricação ou fabricação incompleta do produto, ou, ainda, a falta de uso integral do processo patentado, ressalvados os casos de inviabilidade econômica, quando será admitida a importação; ou II - a comercialização que não satisfizer às necessidades do Mercado” <www.planalto.gov.br/ccivil_03/Leis/L9279.htm> accessed 14 September 2013

²⁹⁹ Scholze, S., ‘Política de Patentes em Face da Pesquisa em Saúde Humana: Desafios e Perspectivas no Brasil’ in *Política de Patentes em Saúde Humana* (Jurídica Atlas, 2001) at 45 -47

³⁰⁰ Article 5 (A)II. Paris Convention for the Protection of Industrial Property, as last revised at Stockholm. 21 UST 1583, 828 UNTS 305.
<www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf> accessed 14 September 2013

Some scholars have interpreted this provision as a way to benefit the local pharmaceutical industry, and also as a kind of limit to unfair competition. This mechanism would also avoid parallel imports since the provision seems to be targeting “the lack of manufacture or incomplete manufacture of the product” which seems to allow or give advantage to local manufacturers to exploit the patent locally on the grounds of national emergency, public interest and abuse of economic power by the right holder. The provision also seems to already acknowledge “importation” or admitting importation of the goods that initially were to be manufactured in the country when economic inability prevented the patentee from producing locally.

In this respect, it has been highlighted that compulsory licences can be granted only to a person or institution technically and economically capable of ensuring efficient exploitation of the patent. Such a case can occur only after proving that the initial right holder is incapable of producing or manufacturing the product to supply in emergency crises or in cases of public interest need.³⁰¹ Compulsory licensing in Brazil is regulated in Decreto n° 3.201/99 (hereinafter Compulsory License Law) later on amended by Decree n° 483/03.T. These Executive Decrees only envisage the compulsory licence regime to address national emergencies and public interest cases, thus compulsory licences for other purposes are to be solved according with the provisions settled within the IP Code.

The other controversial issue brought by the IP Code is the so-called pipeline provision, as it was briefly assessed above, that was initially designed to address patent applications caught up within the transition between the IP legislation prior to TRIPS and current IP Code. Patents for pharmaceutical products and processes were not granted in Brazil before 1996, therefore a mechanism providing patent protection or allowing patent applications to be submitted accordingly with the new standards of protection was not in force before the IP Code. Mainly, the applications were for pharmaceutical products and processes that were still in the clinical trial phase and for which application was not legal in Brazil prior to the TRIPS Agreement.³⁰² This “mailbox provision” as it also became known was supposed to be a temporary provision within the Brazilian IP Code, in accordance with Articles 70(8) and 70(9)– TRIPS.³⁰³ However, this

³⁰¹ Id ut Supra Scholze at 53

³⁰² Id ut Supra Scholze at 48

³⁰³ Article 70(8-9) from the TRIPS Agreement “Article 70 Protection of Existing Subject Matter:

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
 (b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
 (c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part

provision as, will be shown later on, was made permanent in the Brazilian legislation with the amendment of the IP Code in 2001.

Another important challenge is given by the *anuência prévia* or prior consent requirement also created within the amendment of the IP Code. Allegedly, it is aimed at protecting public health interests in Brazil, but its creation brought on another set of challenges. Namely, discrepancies among the criterion used by ANVISA, its delimitations and difference from the examination carried by INPI. Some scholars have even suggested that ANVISA has a veto power over the patent office since patents for both pharmaceutical products or processes depended on the prior consent given by ANVISA.³⁰⁴

3.4. ANVISA: Prior Consent Challenge, and Marketing Approvals

Anuência Prévia or Prior Consent dates from 1999 when a Medida Provisória (Provisional Measure) n° 2,006 of 14 December 1999 amended Article 229 from Lei n° 9,279/96 (IP Code). The reform added three new parts to the article in question, turning it into Article 229-C. Before the reform, Article 229 of the IP Code only referred to certain procedures to be followed for those pending applications that were related to the patentability of processes and procedures for chemical substances,³⁰⁵ but the new reform created the prior consent mechanism for which only ANVISA had the legal competence to verify it.³⁰⁶ This provisional measure became permanent law in 2001 through Lei n° 10196/01. Brazilian scholars have highlighted that the word “*anuência*” within the Brazilian administrative law implies exercising a judgment of both convenience and opportunity, which means manifestation of the administration’s discretionary will.³⁰⁷ Furthermore, the legislation implies that ANVISA in effect expresses a

VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.”

³⁰⁴ See Medida Provisória n° 2.105 – 14 from the 27 of December 2000, reformulates Article 229 from the Lei n° 9.279, and Also see Maristela Basso ‘*Anuência Prévia*’

³⁰⁵ Article 229 C – Lei n° 9, 279: “The provisions of this law will be applied to all pending applications, except with respect to the patentability of substances, matter or products obtained by chemical means or processes and alimentary and chemical-pharmaceutical substances, matter, mixtures or products and medicaments of any type, as well as the respective processes of obtaining or modifying them, which will only be patentable under the conditions established in articles 230 and 231” <www.inpi.gov.br/menu-esquerdo/patente/pasta_legislacao/legislacao-outros-idiomas/lei_9279_ingles_html/> accessed 14 September 2013

³⁰⁶ Article 229 C – Lei n° 10,160/01: “granting a patent for a pharmaceutical product or process it is conditioned to the National Health Surveillance Agency – ANVISA prior consent” English version translated by the author. Original version in Portuguese: Art. 229-C. A concessão de patentes para produtos e processos farmacêuticos dependerá da prévia anuência da Agência Nacional de Vigilância Sanitária - ANVISA.” <www.inpi.gov.br/menu-esquerdo/patente/pasta_legislacao/lei_10196_2001_html> accessed 14 September 2013

³⁰⁷ Borges Barbosa, D., A Inconstitucionalidade da anuência da ANVISA no procedimento de concessão de patentes como manifestação discricionária da Administração Federal. Unpublished (Julho -2004) <denisbarbosa.addr.com/anuencia.doc> accessed 1 December 2012

judgment of both convenience and opportunity when it denies or grants prior consent to the pharmaceutical patent applications examined by this institution.³⁰⁸

No direito administrativo brasileiro, a expressão “anuência” implica exercício de juízo de conveniência e oportunidade, ou seja, de manifestação discricionária da vontade administrativa. (Barbosa-2004)

It has also been pointed out that since the terminology “anuência previa” was not defined either by the law or within the legislation creating it, brought uncertainty as to which is the role of ANVISA in examining pharmaceutical patent claims.³⁰⁹ Also part of the discussion deriving from the legislative reform introducing Prior Consent in Brazil as a patent requirement has to do with the difference in criteria used when examining patents for pharmaceutical products and for second medical uses by the both the Patent Office –INPI, and ANVISA. One is to allow patents for second medical uses, and the other one is said not to grant marketing approvals for these kinds of products. Until a recent decision from the A Primeira Seção Especializada do Tribunal Regional Federal da 2ª Região, no Rio de Janeiro allowed patent protection for second medical uses if these met with the patentability requirements.³¹⁰ Even then, it seems to be a single court ruling and it cannot be said to represent the general understanding about the issue within the whole judiciary system, but it does reflect to a certain extent a better understanding about patent issues on behalf of judges, at least those judges.

Brazil is one of the leading countries in granting and protecting access to medicines. Therefore, patents have to also meet with social requirements. Before amending the IP Code, INPI was the only authority evaluating and examining whether or not patent applications for a pharmaceutical product or process complied with the patentability requirements.³¹¹ After the legislative reform, and with the creation of the prior consent mechanism, the legislator aimed to safeguard access to medicines. Thus, ANVISA became the designated authority assessing the impact of that patent on social needs relating to public interest, issues that in the agency’s opinion are not taken care of by the patent examiners at INPI.³¹² Scholars have shown to be particularly concerned about the complexity hidden behind Article’s 229-C drafting; both delimitation and

³⁰⁸ Idem at 2-3

³⁰⁹ Trigo, Marcela and, Troja, Viviane, ‘ANVISA versus INPI pela concessão de patentes A anuência prévia da ANVISA em relação à concessão de patentes e sua causa de conflitos jurisprudenciais com o INPI’ 8o *Revista Jurídica* (2013) 1-3, 1 <revistavisaojuridica.uol.com.br/advogados-leis-jurisprudencia/80/artigo277163-1.asp> accessed 14 March 2014

³¹⁰ Diário Eletrônico da Justiça Federal da 2ª Região (e-DJ2R) -Cuaderno Judicial, página 1, publicado no dia 6 de Junho, EMENTA PROPRIEDADE INDUSTRIAL - REGISTRO DE PATENTE DE SEGUNDO USO - POSSIBILIDADE EM TESE - NÃO PREENCIMENTO DOS REQUISITOS DO ARTIGO 8o DA LEI 9.279/96 NO CASO CONCRETO.

³¹¹ Rodrigues Junior, E.. and Murphy, B., ‘Brazil’s Prior Consent Law: A dialogue Between Brazil and The United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines’(2006) 16 *Albany Law Journal of Science & Technology*, at 423.

³¹² Brasil, Ministério da Saúde, Portaria nº 345, de 11 de agosto de 2006, Aprova e promulga o Regimento Interno da Agência Nacional de Vigilância Sanitária – ANVISA e da outras providências. Brasília:MDS, 2006. Art. 1º “... tem por finalidade institucional promover a proteção da saúde da população, por intermédio do controle sanitário da produção e da comercialização de produtos e serviços submetidos à vigilância sanitaria...”

parameters of this surveillance mechanism are deemed scarce and possibly create a conflict of attributions between INPI and ANVISA.³¹³

At the beginning, there was no clear knowledge about the criteria used by ANVISA when addressing public health at the time an application for a pharmaceutical patent was being reviewed. After pressing for the agency to publish the guidelines, in 2005 the Agency announced on their website a clarification about Prior Consent for patent applications for pharmaceutical products – Esclarecimentos: anuência Prévia a pedidos de patentes de produtos e processos farmacêuticos, that did not shed any more light than the existent one at that time.³¹⁴ Nevertheless, ANVISA had a veto power according to some scholars³¹⁵ over patent grants by INPI.

If ANVISA assesses the social impact of a patent and also has veto power,³¹⁶ then the question in the mind of scholars was how do these two authorities solve controversies over criteria. Accordingly, a technical meeting shall be carried out to take into consideration all relevant factors to grant or deny the patent.³¹⁷ Another interesting fact regarding the prior consent requirement is that it was not only conceived to assess the impact on public health concerns, but it was also to be used for traditional knowledge protection as denoted by Medida Provisória nº 2,186-16.

In the past, scholars have stressed the need for the Brazilian patent system to be structured in a manner that emphasises the country's social needs, so patent rights also contribute to the economical and technological development; however, prior consent does not receive endorsement from everyone.³¹⁸ However, other parts of the doctrine did find grounds to implement this mechanism; after all, the TRIPS Agreement allows countries to take measurements as to ensure public health protection.³¹⁹ The fact that a “fourth patent requirement” was created by law, and that this had to be analysed by ANVISA, was deemed incompatible with the Constitution's Article 5 XXIX. The right to claim a patent is given by the constitutional text, and that right shall not be modified by any other norm that conditions the right to comply with the will of others; in this case ANVISA.³²⁰

³¹³ Wolff, Maria Thereza, and De Bessa Antunes, Paulo; ‘Patentes de Segundo Uso Médico’ (Jan/Fev 2005) 74 *Revista da ABPI*, 48 – 61.

³¹⁴ ANVISA, Medicamentos, ‘Esclarecimentos: Anuência Prévia a pedidos de patentes de produtos e processos farmacêuticos’ (12 de abril 2005)

³¹⁵ Basso, M., ‘Preliminary Background Paper on Prior Consent for Pharmaceutical Products by ANVISA in Brazil’ Unpublished, (April – 2005), <www.wissensgesellschaft.org/themen/publicdomain/priorconsent.pdf> accessed 30 November 2012

³¹⁶ Rodrigues Junior, E., and Murphy, B., ‘Brazil's Prior Consent Law: A dialogue between Brazil’

³¹⁷ Basso, M., ‘Preliminary Background Paper’

³¹⁸ Borges Barbosa, D., Uma Introdução À Propriedade Intelectual, at 429.

³¹⁹ Basso, M., ‘A Anvisa e a concessão de patentes farmacêuticas’, Instituto de Tecnologia do Paraná Agência Paranaense de Propriedade Industrial - APPI, (18 outubro 2004). <www.deolhonaspatentes.org.br/media/file/Publicacoes/Basso_appi_itp_anvisa.pdf> accessed 30 November 2012

³²⁰ Borges Barbosa, D., ‘A proibição, pela ANVISA, de reivindicações de uso farmacêutico’, *Usucapião de Patentes e Outros Estudos de Propriedade Industrial*, (Ed. Lumen Juris – 2006) 715.

It is still not clear how INPI and ANVISA communicated, and what guideline for criteria was used when assessing societal impact on a patent for a pharmaceutical product. INPI and ANVISA do not only seem to be colliding when it comes to the criteria used to grant a patent, but also it has been found that INPI actually grants patent protection for second medical uses; ANVISA clearly stated in 2004³²¹ that that institution will not grant prior consent for second medical uses. In other words, by ANVISA denying prior consent, INPI has to deny the patent since this agency cannot grant a patent if there is no prior consent.

It has been highlighted that ANVISA was examining patent applications under higher and stricter standards than those carried out by INPI.³²² The fact is that ANVISA's guidelines were kept secret as assured by scholars, and given the agency's ambiguity in the resolutions enacted by it.³²³ The Prior consent mechanism raised the question of compliance with the TRIPS Agreement, despite being envisaged to protect and address public health concerns that were also recognised within the DOHA declaration. In this regard, Article 63 (1) of TRIPS states that all regulations should be publically displayed as to enable both right holders and users to become acquainted with the legislation in force.³²⁴

Allegedly, in 2008 after several years of pressure both at the national and international level,³²⁵ ANVISA published a formal resolution "clarifying" the extent of its attributions when examining patent application submitted to it by INPI. This administrative Resolution 45 – Resolução N° 45 – in Article 4° ratified to a certain extent prior consent as a fourth requirement when stating that "after receiving patents application submitted by INPI, ANVISA will perform the prior consent analysis in light of patentability requirements and other criteria given by law."³²⁶ This Resolution N° 45 also gave evidence on ANVISA's discretionary power when examining patent applications by envisaging the request of further requirements from the applicants so as to keep with the analysis.³²⁷ Beyond providing the public with the aforementioned Resolution, it seemed to have failed in disclosing the real criteria used to actually determine the public health aspect embedded within prior consent.

³²¹ Rodrigues Junior, E., and Murphy, B., 'Brazil's Prior Consent Law: A dialogue Between Brazil'

³²¹ Basso, M., 'Preliminary Background Paper'

Also for further insight see ANVISA

³²² Idem

³²³ Basso, M., 'Preliminary Background Paper'

³²⁴ Article 63 (1) from TRIPS Agreement "Laws and regulations, ..., made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published."

³²⁵ Carvalho, F., 'Brazil and the Defence of Public Health: Do as I say, Not as I do', Intellectual Property Watch, (17 February 2011) <www.ip-watch.org/2011/02/17/brazil-and-the-defence-of-public-health-do-as-i-say-not-as-i-do/> accessed 20 November 2012

³²⁶ Brasil, Ministério da Saúde, Resolução N° 45, de 23 de Junho de 2008, Dispõe sobre o procedimento administrativo relativo à prévia anuência da Anvisa para a concessão de patentes para produtos e processos farmacêuticos, Brasília:ANVISA, 2008. See Art. 4°

³²⁷ Idem, See Art. 4° §1 – 5° §1,2.

Another argument against Prior Consent is that this mechanism is deemed discriminatory, since it only affects pharmaceutical products and processes. In light of the TRIPS Agreement, it has been suggested that under Article 27- TRIPS patent applications shall not be examined under different grounds than those of novelty, inventive step and usefulness, since prior consent could be used in a sensitive fashion to cope with the goals settled within Articles 7 and 8 of the agreement.³²⁸ Article TRIPS 27.2³²⁹ may allow countries to deny pharmaceutical patents on grounds related to public health concerns, however, the issue at stake is the legality of Prior Consent and the right in including a second agency to take part in the examination procedure of determined patent applications.³³⁰

In this respect, attributing discretionary powers to a national agency to deny or grant patent rights on the basis of judgment of both convenience and opportunity according to the agency's will seems to be incompatible with the constitution, since this is the one that creates substantive rights by examining the legal requirements in determined procedures.³³¹ Part of the illegitimacy of ANVISA seemed to initially rely on the secrecy held related to both the guidelines used to protect or approach the societal impact of a patent and the veto power itself. Eight years later the Agency published a Resolution actually addressing the criterion defining the social aspect³³² analysed by them. This issue will be addressed within the concluding remarks.

INPI published its guidelines in 2002, but nothing within these redirect applications to the other agency, or make a difference among inventions.³³³ The Patent Office has shown reluctance in acknowledging both ANVISA's rulings or attributions, and accordingly the national health institute has denied 119 patents. Thus far, INPI has never disclosed the reports, and generic industry was not allowed to make use of the knowledge embedded in the applications to produce needed medicines.³³⁴

Given the confusion within the roles of each agency, INPI, in 2007, sought from the Advocacia Geral da União – Brazilian Attorney-General (hereinafter AGU) to intervene by clarifying or delimiting ANVISA's role.³³⁵ Later on in 2009, AGU issued Parecer N° 210/PGF/AE/2009 settling the conflict of competences in

³²⁸ Articles 7&8, TRIPS and Murphy *ut supra* 70

³²⁹ Article TRIPS 27.2

³³⁰ See further 2 part of Beas and Murphy article, specially Carlos Correa argumentation, at 451

³³¹ Borges Barbosa, D., 'A Inconstitucionalidade da anuência da ANVISA no procedimento de concessão de patentes como manifestação discricionária da Administração Federal' Unpublished (Julho -2004) 19<denisbarbosa.addr.com/anuencia.doc> accessed 20 November 2012

³³² Brasil, Ministério da Saúde, Resolução-RDC N°21, De 10 de Abril de 2013, Altera a Resolução - RDC no 45, de 23 de junho de 2008, que dispõe sobre o procedimento administrativo relativo à prévia anuência da Anvisa para a concessão de patentes para produtos e processos farmacêuticos, Brasília:ANVISA, 2013

³³³ Instituto Nacional da Propriedade Industrial, Diretoria de Patentes, 'Diretrizes de Exame de Patentes' Dezembro 2002. *Also see* Basso, M., 'Preliminary Background Paper on Prior Consent for Pharmaceutical Products by ANVISA in Brazil'

³³⁴ Carvalho, F., 'Brazil and the Defence of Public Health' (2011)

³³⁵ AGU – Procuradoria-Geral Federal is the competent authority to settle disputes between public organs in accordance with art. 4° da Lei Complementar n° 73, de 10 de fevereiro de 1993, a Lei Orgânica da Advocacia-Geral da União. < http://www.planalto.gov.br/ccivil_03/Leis/L9469.htm> accessed 20 November 2012

favour of INPI.³³⁶ In this respect, the ruling established that INPI is the only authority with legal competence to examine patent applications on the basis of novelty, inventive step and industrial applicability.³³⁷ Therefore, this limited ANVISA to performing public health assessments over patent applications for pharmaceuticals. To complicate things further, during the same year the Ministério Público Federal (MPF) sought the nullity of Parecer N° 210/PGF/AE/2009 in a public civil action with a request for preliminary injunction before the 7ma Vara Da Seção Judiciária Do Distrito Federal. In this process the MPF requested 7ma VFDF to ratify ANVISAS competence to examine pharmaceutical patent claims in light of the patentability requirements foreseen within the IP Code since ANVISA under Article 18(I) of the IP Code also allowed the agency to deny patents contrary to public health needs.³³⁸ This Processo n° 46656-49.2011.4.01.3400, 7ª VFDF³³⁹ denoted the misinterpretation of Article 18(I) of the IP Code on behalf of ANVISA, who allegedly misunderstood its role in addressing the public health concern, but the 7ma VFDF instead ratified AGU's ruling where ANVISAS competences are delimited to assessing the public health aspect in patent claims.

Scholars suggest that ANVISA is now restricted from examining patent applications,, and therefore is it no longer possible for applicants to request information about novelty and inventive steps as Resolution N° 45 allowed it to do in the past.³⁴⁰ Before AGU's ruling, ANVISA in fact rejected 119 applications from a total of 1346 applications submitted to the agency. The ruling also acknowledged the need to enact a regulation establishing the terms of the collaboration between the Patent Office and the National Health Institute and to also make clear the distinction between their roles and duties in light of the requirements settled in the new IP Code.³⁴¹ In this respect, and amid growing confusion about ANVISA's role, the Federal Government created via Portaria MS/MDIC/AGU no 1.956, dated 16 August 2011 an Interministerial Working Group (Grupo de Trabalho Interministerial-GTI) with the purpose of analysing and to suggest both criteria and procedures to carry out the prior consent analysis by ANVISA in light of the Article 229-C.³⁴² Within their report, the GTI delimits

³³⁶ Procuradoria-Geral Federal, 'Procuradurias Federais junto ao INPI e à ANVISA', Parecer N: 210/PGF/AE/2009.

³³⁷ Shadlen, K., 'The Rise and Fall of "Prior Consent" in Brazil' (UK-2011) 3 *The WIPO Journal* 1, 103-110 at 107.

³³⁸ Article 18 (1) from Lei n° 9.279

³³⁹ Procuradoria Da República No Distrito Federal, 'Ministério Público Federal - INICIAL - SAÚDE - Nulidade do parecer da AGU - ICP 3253-2008-85\o', Processo n° 46656-49.2011.4.01.3400, 7ª VFDF<www.prdf.mp.br/impressa/arquivos_noticias/acp-patentes.pdf> accessed 14 March 2014

³⁴⁰ Idem

³⁴¹ Procuradoria-Geral Federal, 'Procuradurias Federais junto ao INPI e à ANVISA', Parecer N: 210/PGF/AE/2009. Conclusão, 51 §e.

³⁴² The GIT was integrated by representatives of the Ministry of Health - Ministério da Saúde (MS), Ministry of Development, Industry and Foreign Trade -Ministério do Desenvolvimento, Indústria e Comércio Exterior (MDIC) (MDIC), the Attorney General of the Union - da Advocacia-Geral da União (AGU), the National Health Surveillance Agency - Agência Nacional de Vigilância Sanitária (ANVISA) and the National Institute of Industrial Property - Instituto Nacional da Propriedade Industrial (INPI) whom prepared the report that was published within Portaria Interministerial n°. 1065 de 24 de maio de 2012. See Trigo, Marcela and, Troja, Viviane, 'ANVISA versus INPI pela concessão de patentes' ut supra at 3

the scope of action of each of the institutions, addresses the terms of cooperation between both INPI and ANVISA and also provides a 5-step flowchart that illustrates the procedure when carrying out the prior consent process.³⁴³

To prevent medicines from reaching the market, when patents for these would have a negative effect on public health related matters, according to ANVISA's assessment, it has been suggested to do so at the moment when marketing approvals are applied for.³⁴⁴ Thus, ANVISA in RDC n° 21 has finally made public the guidelines used to assess the public health aspect within the patent claims channelled via INPI. This Resolution goes further than Resolution n° 45 in terms of defining the scope of prior consent mechanism,, in this respect Article 2(1) reads "anuência previa is a deliberative act from ANVISA carried out in light of Article 229-C of Lei n° 9.279 from 1996, in which the Agency examines the object of the claim in terms of the public health context."³⁴⁵ Furthermore, the aforementioned resolution initially delimits the analysis to the contexts of medicines containing substances forbidden by law,³⁴⁶ patent claims for products or processes that represent an interest to drug policies and pharmaceutical services under the SUS context and does not meet the patentability requirements and other criteria established by the Lei n° 9.279.³⁴⁷ The following articles from the Resolution seem to clarify the context of its analysis established previously in Article 4§1(I-II), however it does not seem to clarify the context of the wording used when addressing that such analysis will also examine the patentability requirements. Since this last issue seems to allow certain interpretation, it will be analysed within the conclusions of the research.

3.4.1. Prior Consent and Second Medical Uses

Given that INPI and ANVISA collide when examining patents for second medical uses, it is only fair to assess the main difference between the points of view of the agencies. On the one hand, INPI considers that once the application for a second medical use meets the novelty and the inventive step then a patent shall be granted; and on the other hand, ANVISA considers that a patent for second

³⁴³Brasília, Grupo de Trabalho Interministerial 'Relatório De Análise E Sugestão De Critérios, Mecanismos, Procedimentos, Obrigações E Possíveis Instrumentos Formais Para Articulação Entre A Anvisa E O Inpi Com Vistas À Execução Do Art. 229-C Da Lei No 9.279/1996' 19 de Janeiro de 2012, 1-9, at 6-9
<bvsms.saude.gov.br/bvs/saudelegis/gm/2012/anexo/anexo_pri1065_24_05_2012.html.pdf>
accessed 15 March 2014

³⁴⁴Carvalho, F., 'Brazil and the Defence of Public Health' (2011)

³⁴⁵Article 2(I) from Resolução-RDC N° 21 dated 10 April 2013. "Prévia anuência: ato deliberativo da Anvisa expedido com vistas ao atendimento do art. 229-C da Lei no 9.279, de 1996, no qual a Agência examina o objeto do pedido de patente à luz da saúde pública"

³⁴⁶Article 4 §1° from Resolução-RDC N° 21 dated 10 April 2013 "Considera-se que o pedido de patente será contrário à saúde pública quando: I- I- O produto ou o processo farmacêutico contido no pedido de patente apresentar risco à saúde; ou"

³⁴⁷Article 4§1°(II) from Resolução-RDC N° 21 dated 10 April 2013. "O pedido de patente de produto ou de processo farmacêutico for de interesse para as políticas de medicamentos ou de assistência farmacêutica no âmbito do SUS e não atender aos requisitos de patenteabilidade e demais critérios estabelecidos pela Lei no. 9.279, de 1996."

medical uses does not fulfil the patentability criteria and that it would also hamper access to public health.³⁴⁸

The discussion on whether granting or denying patents for second medical uses not only concerns the fulfilment of patentability requirements;; it goes beyond this, extending to the constitutionality of the norm and the practice carried out by the agency. Interestingly enough, both the Brazilian Federal Constitution and the TRIPS Agreement stand for and against ANVISA's criteria and overprotective approach.

Both intellectual property rights and health rights are foreseen and protected within the Constitutional. Article 5 XXIX protects intellectual property rights and at the same time the same article takes into consideration social needs:

Article 5: everyone is equal before the law, without distinction whatsoever, guaranteeing Brazilians and foreigners residing in the country the inviolable right to life, liberty, equality, safety and property, as follows:

XXIX – the law shall ensure to the authors of industrial inventions a temporary privilege for its utilization, taking into consideration the social interest, and the technological and economical development of the Country.³⁴⁹

By interpreting the abovementioned constitutional Article, it becomes possible to consider excluding second medical uses from patentability if such uses would interfere with the country's development or their social interests. By denying prior consent to patents for second medical uses, if the law so excluded, the agency seeks to prevent ever greening within the patent system with me-too drugs that could be needed to address national health issues.³⁵⁰

The issue with access to medicines is that as a fundamental right it is also constitutionally protected. Therefore, the challenge is to determine which right weighs more, and to do is this, scholars will most likely need to engage in discussion of a more philosophical and theoretical nature. The human right to health is of great importance, and private rights cannot be considered over the needs of the vast majority. But, the discussion on a general level was assessed within the background of the study.

The rationale arguing against considering that patent rights are a fundamental right goes beyond the scope of pharmaceutical patents per se. A part of the Brazilian doctrine has pointed out that intellectual property rights should have never been foreseen as fundamental rights within the Constitution, since these are economic rights; and given the nature of IP rights this should have been enshrined within economic rights, instead of within the respective constitutional chapter, as this would be by far more suitable.³⁵¹

³⁴⁸ Mitsuuchi Kunisawa, V., 'Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil' (2009) 12 *The Journal of World Intellectual Property* 4, at 297 – 316

³⁴⁹ Artigo 5º, numeral XXIX from the Constituição de la Republica de Brazil de 1988

³⁵⁰ Carvalho, F., 'Brazil and the Defence of Public Health' (2011)

³⁵¹ Proner, C., *Propriedade Intelectual E Direitos Humanos – Sistema Internacional de Patentes e Direito ao Desenvolvimento* (Sergio Antonio Fabri Editor, 2007) at 139.

ANVISA's decision in not granting patents for second medical uses is deemed illegal despite aligning with the agency's criteria, since patent rights are a sort of property protected or guaranteed within the Federal Constitution. Scholars bring to the spotlight the fact that no uniformity regarding second medical uses is found in Brazil, since several court rulings have settled the issue differently, evidencing lack of understanding within the whole framework. These court rulings draw attention to the concept of bad patents since granting them would hamper society's access to medicines.

Scholars have addressed the need for a legal reform shedding light not only on the definition of Prior Consent, but also to the function delimitation for ANVISA's performance or accurate role when examining patents. Due to the ambiguity within the legislation creating the mechanism and the lack of understanding between the two agencies, it is practically impossible to reach an agreement on how neither to examine patent nor to assess the societal impact for the first or a second medical use.³⁵²

On 24 August 2004 the agency released a report on its web page, on the basis of The Collegiate Board's meeting held on 26 November 2003, in which it suggested that examination of patent applications seeking protection for a new use for a chemical substance have shown that those new uses are harmful for public health and for the country's scientific and technological development, with a particular impact on access to medicines. Thereafter, it decided not to grant prior consent for patent applications for second medical uses.³⁵³ This report was categorised as extremely generic, and it also appears to offer a more political answer than a legal one, given that patents for second medical uses are legal within the Brazilian legislative framework.³⁵⁴

In this respect, AGU's ruling shed light on the roles of each agency, but no immediate legislative reform or resolution followed clarifying the rules on how to proceed or assess the public health impact given by a determined pharmaceutical patent. ANVISA has failed to provide the public with a proper explanation on *why* patents for second uses are harmful, but instead the agency has suggested that second medical uses do not meet with the novelty requirement. Anvisa recently published a resolution shedding light on, and perhaps for the first time making public, the criteria used to assess the public health aspect embedded in determined patent applications. This issue will be addressed within the conclusions of the research.

Interestingly enough, patents for second medical uses promote research and innovation since the prohibiting costs of R&D and clinical trials will also reduce considerably. Given that patents protect the investments and the intellectual

³⁵²Mitsuuchi Kunisawa, V., 'The Patentability and Scope of protection of pharmaceutical inventions claiming second medical use- The Japanese and European approaches as possible paradigms for a developing country like Brazil', IIP, (Tokyo – 2008) 16-22.

³⁵³ ANVISA, Esclarecimento sobre Pedidos de Patentes dos Produtos e Processos Farmacêuticos. <www.anvisa.gov.br/divulga/informes/2004/250804.htm> accessed 14 September 2013

³⁵⁴ Wolff, M., and De Bessa Antunes, P., 'Patentes de Segundo Uso Médico' (Jan/Fev 2005) 74 *Revista da ABPI*, at 48 – 61

efforts carried out, it is highly advisable that countries provide a well-structured patent system.³⁵⁵

The aspirin case becomes relevant when assessing the discussion on whether patents for further medical uses should be allowed. It is a well-known fact that this chemical compound (Acetylsalicylic Acid) was initially used as an antipyretic –medicine to prevent or control fever- and to prevent swelling. Later it was found that the same active ingredient could be used to prevent myocardium heart attacks and brain vascular diseases. Hence, patent protection granted for those uses demonstrated how second uses are necessary and that these have been granted in the past despite the assertions about extending patent protection for Aspirin in a fictitious manner.

One thing to take into consideration when analysing second medical uses is the fact that nothing within the Brazilian legislation regarding intellectual property rights excludes or forbids them. Instead, what it is regulated and excluded are techniques and surgical methods applied to humans or animals, methods destined to diagnose and therapeutic methods.³⁵⁶ The Brazilian legislation distinguishes between therapeutic methods, surgical methods and techniques applicable to humans and animals and diagnoses methods. INPI also forbids patent applications for the protection of therapeutic methods.³⁵⁷

3.5. Intellectual Property Rights and its Social Function

Within the public health and access to medicines discussion in Brazil, scholars constantly bring up another factor, that is, the social function “requirement” established by the political constitution.

The debate seems to be divided between those who argue on whether or not intellectual property rights are conditioned to the social and economical development of the country; and others point out that the impact of patent protection on society is that of fulfilling social and economical needs according with the economical and technological development within the country.³⁵⁸

These arguments about the pre-condition to grant or guarantee a temporary property right rely on the need to limit a right to become superior to other rights. It has been highlighted that as efficient as the patent system might be, it will always have its limits when these rights turn into a threat to public health and public order. Acknowledging the existence of the patent system also implies recognition or acknowledgement of the social benefits brought by this system to the Brazilian society. The patent system is not an absolute guarantee, but on the

³⁵⁵ Idem at 49-50

³⁵⁶ Artigo 10 (VIII) from Lei 9.279, “Art. 10. Não se considera invenção nem modelo de utilidade: VIII - técnicas e métodos operatórios ou cirúrgicos, bem como métodos terapêuticos ou de diagnóstico, para aplicação no corpo humano ou animal; e...”

³⁵⁷ Brasil, INPI, Diretrizes de Exame de Patentes, v01.00, Dezembro 2002

³⁵⁸ Bianchi Cerqueira, L., ‘O Princípio da função social da Propriedade e as Patentes – passado e futuro’ (Maj/Junho 2006) 82*Revista da ABPI*, at 41 – 59

contrary it is conditioned to the legal principles conceived by the legal system itself (public interest).³⁵⁹

The social function principle in Brazil is a Constitutional right and a limitation to the right of property, as assessed in Article 5 (XXIII) and Article 170³⁶⁰ of the Constitution. Even though the aforementioned article refers to the economic order, this article highlights the principles contained within the Constitution. Therefore, private property is also conditioned to the social principle function. The rationale behind this conditioning seems to rely on possible disparities among the owner's interest (private) and the general one. Scholars have suggested that the right to property in Brazil, beyond being an individual institution for ownership, protection and enjoyment is a privilege granted by public will. And this is why the social function finds its supremacy in the public interest over private interest in Brazil. Attention has also been drawn to the fact that the Brazilian legislator primarily looked forward by protecting the productive and technological activities in the country, since the Constitution also emphasises these issues.³⁶¹

The paradox of the legal monopoly given by patents to the right holder is also addressed within the aforementioned social function rationale. On the one hand, the patent system is conceived of as an incentive or a way to promote technological innovation, but on the other hand the reward given to the owner for a determined period of time might be seen as contrary to fair competition.

3.6. Competition and Compulsory Licences in Brazil

The monopoly given to a right holder has been widely debated in many countries. The challenge for the Pharmaceutical industry is to demonstrate that patents do promote innovation, that these rights do not severely hamper access to essential medicines and that the patent system accomplishes its goal of promoting innovation in various fields i.e. for neglected diseases.

The benefits of the patent system may seem difficult to prove, given that many reports showcase it as detrimental for access to medicines. In 2001 Médicines Sans Frontières (hereinafter MSF) released a report where the humanitarian aid organisation asserted that up to 1999 from 1,393 new drugs approved for

³⁵⁹ Grau – Kuntz, K., 'Direito de Patentes – Sobre a Interpretação do Artigo 5º, XXIX da Constituição Brasileira' (Jan/Fev, 2009) 98*Revista da ABPI*, at 42 – 48

³⁶⁰ Constituição da República do Brasil - 1988 "**Article 5:** All are equal before the law, without discriminations of any nature, thus ensuring to both Brazilians and foreigners residing in the country the inviolable right to life, liberty, equality, security and property, as follows: XXIII property must observe its social function; **Article 170:** the economic order is founded on the value of human work and free enterprise, aiming to ensure everyone to live with dignity accordingly with the social justice mandates within the following principles: I- National sovereignty; II- Private Property; III- Social Function; IV- Fair Competition; V- Consumers rights; ..." Translation by the author. Original text in Portuguese" Translation by the author. Original text in Portuguese <www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm> accessed 14 September 2013>

³⁶¹ Fernandes Campilongo, C., *Política de Patentes e o Direito da Concorrência* in *Política de Patentes em Saúde Humana* (Ed. Atlas, 2001) at 154 – 191.

commercialisation only 13 were of relevance for tropical diseases.³⁶² This report also suggested the failure of the patent system in terms of innovation within the field of neglected diseases. Certainly there are opposing views on the system's efficiency, nevertheless the balance between both private and public interests remain unachieved.

Pharmaceutical patents, as it is widely suggested, may contribute with elevated drug prices³⁶³, and therefore countries must find measures to counterbalance such an effect. In Brazil, compulsory licences are not only a counter measure for those who abuse economic power and market position, but also a way to ensure access to essential medicines. The TRIPS Agreement and several multilateral and bilateral agreements envisage compulsory licences as a method to limit monopoly. Prior to providing protection for pharmaceutical inventions in Brazil, one way to create competition in the local market was to allow the national industry to copy the products from multinational companies dominating the international market.

It has been argued that inventors unfold in a context of imperfect competition since IP protection "creates" barriers to competition, thus it is necessary to limit the creation of these barriers while guaranteeing both economic and social rights.³⁶⁴ Within the monopoly discourse, it has been asserted that right holders see their rights limited due fair competition intervention in an attempt to reduce production costs to ensure consumers access to the new product.³⁶⁵ This limitation to individual rights is given by the Constitution. Accordingly, right holders receive a monetary reward as long as society finds their invention useful, and as long as it does not collide with social interest.

Compulsory licences in Brazil may be granted if the right holder "exercises IP rights in an abusive manner or by means of it practices abuse of economic power that is proven under the terms of the law by an administrative or court decision."³⁶⁶ Among these abusive behaviours, failing to work the patent, unless justifiable, seems to fall within the grounds to grant such licence. In this respect, Article 68 § 1(I) from the IP Code establishes that failure to exploit or the non-exploitation of a patent in a period of three years from the date the patent was granted could result in the enactment of a compulsory licence.

Allegedly, compulsory licences are normally used as a countermeasure to monopolies or anti-competitive practices. But these can also be granted in cases of a national emergency or public interest as regulated in Decreto nº 3.201

³⁶² *Médecines Sans Frontières*, 'Fatal Imbalance in Research and Development for Drugs for Neglected Diseases', *Access to Essential Medicines Campaign and the Drugs for Neglected Diseases Working Group I*, September 2001

³⁶³ "t Hoen, Ellen, 'TRIPS, pharmaceutical patents and access to essential medicines: A long way from Seattle to Doha' 3*Chicago Journal of International Law*1(2002)27-46

³⁶⁴ Andrade Capp, D., 'A Função Social Da Propriedade Intelectual', at 81-83

³⁶⁵ Borges Barbosa, D., *Uma Introdução à Propriedade Intelectual* (2da Edição, 2003) at 100

³⁶⁶ Lei nº 9.279/96, Article 68: A patentee will be subject to have his patent licensed compulsorily if he exercises the rights resulting therefrom in an abusive manner or by means of it practices abuse of economic power that is proven under the terms of the law by an administrative or court decision: § 1º the following cases shall be also object of compulsory licensing."

regarding *ex officio* compulsory licences.³⁶⁷ Other methods to correct anti-competitive practices seem to be price control policies that could also be achieved by promoting production of generic medicines. Controlling pharmaceutical prices seems to be complicated, as it also requires finding out prices of the same medicines in neighbouring countries, which is done to settle adequate prices without either severely putting in jeopardy the profits of the right holder in the country where the price control policy exists, or restraining affordability.³⁶⁸

Even when compulsory licences may be enacted the right holder will be compensated accordingly, but precisely determining the amount or “adequate remuneration” may be challenging. Several suggestions have been drawn to address the issue, for instance the WHO issued the “Remuneration Guideline for Non-Voluntary Use of a Patent on Medical Technologies” where royalty setting is portrayed as a not very complicated method to compensate the right holder.³⁶⁹ Another option to calculate the remuneration could be “by basing it on the economic value of the patent, which is then discounted by certain factors, by taking the economic value into account but not using it as a basis, or on the value that the patent generates to the licensee”³⁷⁰. Ultimately though, the final decision on setting the remuneration relies on the Government enacting the compulsory licence.

Abuse of either dominant position or relevant market are considered punishable behaviours within Article 36 from Lei n° 12.529/11.³⁷¹ Determining unfair

³⁶⁷ Brasil, Presidência da República, Decreto N° 4.830/03, de 4 de setembro de, 2003, Dá Nova redação aos arts. 10,20,50,90 e 100 do Decreto N°3.201, de 6 de outubro de 1999, que dispõe sobre a concessão, de ofício, de licença compulsória nos casos de emergência nacional e de interesse público de que trata o art. 71 da Lei n° 9.279, de 14 de maio de 1996. Brasília, 2003.

³⁶⁸ Fernandes Campilongo, C., Política de Patentes e o Direito da Concorrência, at 166

³⁶⁹ Love, James, ‘Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies’ 18 *Health Economics and Drugs* TMC Series (World Health Organization WHO/TCM/2005.1) 1-104, at 19

<www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf> accessed 18 March 2014

³⁷⁰ Välimäki, Elli, ‘Calculation of Royalties in Compulsory Licensing of Pharmaceutical Patents in Europe – How Much is Justified?’ *Nordic Journal of Commercial Law* (Special Edition 2011) 1-27, 25.<www.academia.edu/1421481/Calculation_of_Royalties_in_Compulsory_Licensing_of_Pharmaceutical_Patents_in_Europe_How_Much_is_Justified?login=dmchd@yahoo.com&email_was_taken=true&login=dmchd@yahoo.com&email_was_taken=true&login=dmchd@yahoo.com&email_was_taken=true> accessed 18 March 2014, For more information and other theories concerning adequate remuneration *also see* Bond, E., and Saggi, K., ‘Compulsory Licensing, price controls, and access to patented foreign products’, Working Paper No. 12-W05, (Vanderbilt University – April 2012) 1-26. <www.vanderbilt.edu/econ/wparchive/workpaper/vu12-w05.pdf> accessed 15 November 2012

³⁷¹ Brasil, Presidência da República, Lei n° 12.529, de 30 de novembro de 2011, Estrutura o Sistema Brasileiro de Defesa da Concorrência; dispõe sobre a prevenção e repressão às infrações contra a ordem econômica; altera a Lei no 8.137, de 27 de dezembro de 1990, o Decreto-Lei no 3.689, de 3 de outubro de 1941 - Código de Processo Penal, e a Lei no 7.347, de 24 de julho de 1985; revoga dispositivos da Lei no 8.884, de 11 de junho de 1994, e a Lei no 9.781, de 19 de janeiro de 1999; e dá outras providências. Brasília-2011. Art. 36. Constituem infração da ordem econômica, independentemente de culpa, os atos sob qualquer forma manifestados, que tenham por objeto ou possam produzir os seguintes efeitos, ainda que não sejam alcançados: (II) dominar mercado relevante de bens ou serviços; and (IV) - exercer de forma abusiva posição dominante

competition is not part of the National Patent Office's attributions, and therefore it is the Conselho Administrativo de Defesa Econômica – Administrative Council for Economic Defence (hereinafter CADE) that is the Governmental body in charge of providing the interested party with either an administrative or judicial decision to sanction the misconduct. In general terms, a third party interested in obtaining a compulsory licence to exploit a patent that is currently not being exploited or for which the right holder is overusing its right, must request CADE to initiate an investigation in order to find out whether or not anti-competitive practices actually exist. If restrictive practices are proven, CADE's decision needs to be taken to INPI for the compulsory licence to be obtained to manufacture the said product.³⁷²

It has been suggested that a compulsory licence may be also used as a legal mechanism to limit or suppress the rights of a patent holder when they have been involved in abusive practices when making use of their exclusive right. The mechanism aims to correct anti competitive behaviours. Compulsory licences are of great importance for the patent system, as highlighted by several authors, since its acceptance and establishment by law allows governments to balance public and private interests when they are against the legal framework.³⁷³

According to some authors, the pharmaceutical industry finds compulsory licences to be a threatening mechanism for future research and development since revenues will be limited to the production costs, which will probably not cover the full R&D expenses.³⁷⁴ This happens due to the price reduction suffered by the product marketed under compulsory licensing. Thus far, the only country making use of the import system through compulsory licence according to the World Trade Organization (WTO) is Canada. Moreover, Brazil made use of TRIP's flexibility in 2007 when it issued a compulsory licence to supply the internal market with the anti-retroviral Efavirenz after failed negotiations with MERCK.³⁷⁵ This compulsory licence was prolonged in 2012 for a period of five years.³⁷⁶

Some benefits are embedded in enacting compulsory licences. Part of the doctrine highlights that two of the benefits for licensees derived from the use of this mechanism are the possibility to promote the national industry's development through production of the product licensed, and it may considerably reduce both risks and costs in producing the medicine.³⁷⁷ Other scholars deem compulsory

³⁷² See Andrade Capp, D., 'A Função Social Da Propriedade Intelectual' at 94

³⁷³ Steffen Guisse, M., 'O Brasil e a Ordem Multilateral do Comércio Internacional: Compatibilização entre a Proteção de Patentes e Políticas Nacionais de Saúde Pública' in *Comércio Internacional, Patentes e Saúde Pública* (Ed. Juruá, 2008) at 122

³⁷⁴ Rozek, R., and Rainey, R., 'Broad-based compulsory licensing of pharmaceutical technologies – Unsound public policy' (2001) 4 *The Journal of World Intellectual Property* 4

³⁷⁵ Brasil, N., and Costa, N., 'Artigo Assinado Sobre o licenciamento compulsório da patente de Efavirenz' in *ABIFINA Informa* (Edição 7, 2007)

<www.abifina.org.br/informaNoticia.asp?cod=191> accessed 14 September 2013

³⁷⁶ Brasil, Presidência da República, Decreto nº 7.723, de 4 de maio de 2012, Prorroga o prazo de vigência do licenciamento compulsório, por interesse público, das patentes referentes ao Efavirenz para fins de uso público não comercial, de que trata o Decreto no 6.108, de 4 de maio de 2007. Brasília, 2012

³⁷⁷ Fernandes Campilongo, C., *Política de Patentes e o Direito da Concorrência*, 166

licences as a discouraging mechanism for the pharmaceutical industry, arguing that pharmaceutical companies will tend to spend less on R&D for essential medicines if there is no real certainty in recouping their investment due to losing monopoly powers to the government's compulsory licensing policies.³⁷⁸

3.6.1. Exhaustion of Rights (First Sale Doctrine) and Parallel Imports

Exhaustion of rights may play a role within the access to medicines discourse. Therefore, scholars suggest that patent rights may be limited by having a clear national exhaustion of rights regime, given that in theory once the right is exercised by either selling the product (the *first sale doctrine*) or obtaining economic exclusivity granted to its owner, the rights will cease to exist.³⁷⁹

The exhaustion principle is settled in Article 43 (IV) of the IP Code.³⁸⁰ This provision envisages a limit to the patent holder's rights by disregarding them from preventing others to make use, produce or distribute the patented product or the process when the product per se has already been manufactured in accordance with a process or product patent that has been introduced onto the domestic market directly by the patent holder or with his consent.³⁸¹ Admittedly, patent rights grant exclusivity, but this is not an absolute and unlimited right.

An important aspect to take into consideration is that even though the patent holder may not be able to exercise in full his exclusive rights, given that this has been fulfilled with the first sale doctrine, if a third party as an exception makes use of patent rights, this use cannot interfere with or jeopardise the patent holder's legitimate interests.³⁸² Exhaustion of rights or the first sale doctrine, as commonly referred to, also relates to parallel imports and compulsory licences within the IP Code. On the one hand the principle is settled, but on the other scholars have pointed out certain issues in terms of the consent given by the patent holder in cases of parallel imports.³⁸³ Scholars have argued that Brazil follows the rules for national exhaustion of rights since the legislator includes the words *national market* in the legislation.³⁸⁴ However, the fact that Brazil belongs to MERCOSUR, which is an economic union, might pose another set of challenges in relation to parallel imports.

In principle, as soon as the patented product has been sold in the country where the patent has been obtained, the right holder cannot interfere with the product's free circulation within that market. With this, the patent holder's right should be

³⁷⁸ Pogge, T., 'Intellectual Property Rights and Access to Essential Medicines' (2007) Policy Innovations

³⁷⁹ Borges Barbosa, D., Uma Introdução À Propriedade Intelectual, at 380

³⁸⁰ Rocha Furtado, L., 'Sistema de Propriedade Industrial no Direito Brasileiro', at 56

³⁸¹ Article 43(IV) from Lei n° 9.279, making reference to Article 42 provision on rights granted by a patent.

³⁸² Fonseca, A., 'Exatão Internacional de Patentes e Questões Afins', in Márcia Flávia Santini Picarelli, Política de Patentes em Saúde Humana, (Ed. Jurídica Atlas, 2001) at 227

³⁸³ Sherril, H., 'As Importações Paralelas Na Lei N° 9.279, De 14 de Maio de 1996, E O MERCOSUL' (NOV/DEC 1996) 25 *Revista Da ABPI* at 23

³⁸⁴ Moreira Do Patrocínio, D., 'Princípio da Exatão dos Direitos de Propriedade Intelectual E A Importação Paralela' (SET/OUT 2006) 84 *Revista da ABPI*, at 52

in theory exhausted. However, the Brazilian IP Code brings to the spotlight the fact that patented products or products manufactured according with the process patented can be imported or commercialised by third parties as long as the original right holder has either placed them himself first or he has consented to such an import.³⁸⁵ Precisely, the aforementioned consent is considered to be an implied consent, since the Government takes it from the patent holder to supply the internal market when the right holder i.e. has neglected his duty or denied to work the patent within the time frame given by law, since this behaviour is considered to be an abusive practice.³⁸⁶

Compulsory licences can also be considered as a way to exhaust rights. Article 68 §4 from the IP Code foresees international exhaustion by allowing a third party to import a product manufactured according to a process or product patent,³⁸⁷ since according with the legislation the right holder cannot prevent free circulation of the product within the local market when such a situation falls within the context of Article 68 §3 and §4 from the IP Code.³⁸⁸ On the other hand, parallel imports are envisaged with the aim of supplying the national market in determined cases, namely as an exception to the rule settled by law. Thus, allowing parallel imports on a general basis is believed to be detrimental to the patent system, since companies would decrease productivity and efficiency when no regard to their efforts is given.³⁸⁹

Some scholars have asserted that compulsory licences granted to correct abusive practices such as failure to comply with the local working requirement, or insufficient local supply are the most important provisions foreseen within Brazil's IP code.³⁹⁰ It is said to express the national concern over insufficient national supply and also provides determined requirements that must be fulfilled by the third party seeking to obtain a compulsory this licence. This requirement is not generally established within the international framework, since, as previously established, economic unfeasibility needs to be proven before the compulsory licence to import the product can actually take place. In this respect, Article 68 from the IP Code does not necessarily aim at demanding the local working requirement, but instead aims to prevent an import monopoly on behalf of the

³⁸⁵ Artigo 68 §4, - Lei N° 9.279: "No caso de importação para exploração de patente e no caso da importação prevista no parágrafo anterior, será igualmente admitida a importação por terceiros de produto fabricado de acordo com patente de processo ou de produto, desde que tenha sido colocado no mercado diretamente pelo titular ou com o seu consentimento." (Translation) "In the case of importation for exploitation of a patent and in the case of importation provided for in the previous paragraph, the importation by third parties of a product manufactured according to a process or product patent will equally be allowed, provided it has been placed on the market directly by the patentee or with his consent."

³⁸⁶ Sherril, K., 'As Importações Paralelas Na Lei N° 9.279' at 24

³⁸⁷ Artigo 68 §4 from Lei n° 9.279 and *also see* Sherril, H., 'As Importações Paralelas Na Lei N° 9.279' at 24-25

³⁸⁸ Article 132 from Lei n° 9.279: "A trade mark owner may not: III - prevent the free circulation of products placed on the internal market by himself or by another with his consent, without prejudice to the provisions of §§ 3 and 4 of article 68..."

³⁸⁹ *Idem* Sherril, H., at 23

³⁹⁰ Figueira Barbosa, A.L., 'Importação, Trabalho Obrigatório, Caducidade e Licença Compulsória' (NOV/DEC 1996) 25 *Revista Da ABPI* at 27-37

patent owner since this would not fulfil the goal of promoting national development and technology transfer.³⁹¹

The United States of America contested the aforementioned provision, regarding it as a breach of TRIPS and an infringement of Articles 27-28 from the Agreement. On the other hand, Brazil argued that both Article 27 from TRIPS and Articles 5 and 8 from the Paris Convention entitled the Government to take necessary measures to protect public health concerns and also to avoid or correct anti-competitive behaviours on behalf of the right holder.³⁹² After a lengthy process, the case that was only brought to consultations concluded with the United States withdrawing the complaint before the Dispute Settlement Body. Allegedly, the measure had to do with major commercial interests that were at stake for the complaining country.³⁹³

Generally, parallel imports could be considered as a restriction to patent rights. However, the TRIPS Agreement also allows member countries to choose either the regime for national or international exhaustion of rights; whichever complies with the principles of national or regional treatment and the most favoured nation.³⁹⁴ In this respect, scholars assert that parallel imports, although “illegal” at first if the country in question implements an international exhaustion regime, are “legalizing” parallel imports³⁹⁵, since to a certain extent in the context of a regional market it is acceptable and justified to favour reciprocity among neighbouring nations while also using this as an element to incentivise competition among the national industries of the countries belonging to the regional market.³⁹⁶ This alleged “reciprocity” does not seem to be a widely accepted argument since the pharmaceutical industry opposes parallel imports on the basis of price discrimination given that prices will not be settled by the company, thus losing revenues that could be allocated for R&D. So price control policies are somewhat imposed on the products imported via this mechanism, and according to the industry parallel imports may represent a threat to public safety since wholesalers and distributors may not be as reliable as the originator.³⁹⁷

³⁹¹ Scholze, S., ‘Fabricação Local, Licença Compulsoria E Importação Paralela Na Lei de Propriedade Industrial’ (SEP/OUT 2001) 54 *Revista Da ABPI* at 9-12

³⁹² Gomes Brunner, A., ‘As Patentes Farmacêuticas E A Licença Compulsória: O Fin de uma Batalha entre os Estados Unidos e o Brasil’ (Nov/Dez 2001) 55 *Revista Da ABPI* at 26-30

³⁹³ *Ibid* at 29-30

³⁹⁴ Article 3-4, and 6 from TRIPS Agreement

³⁹⁵ Keith, Markus, ‘Parallel Imports In Pharmaceuticals: Implications For Competition And Prices In Developing Countries’, WIPO -Final Report to World Intellectual Property Organization (April 2001) 1-22, 2. <www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf> accessed 18 March 2014

³⁹⁶ Andrade Capp, Débora, (ed.) ‘Função Social da Propriedade Intelectual – A “Quebra” de Patentes’ in *Límites Jurídicos da Regulação e Defesa da Concorrência* (Porto Alegre, Sergio Fabris, 2003) 87

³⁹⁷ For further insight about this arguments see Abbott, Frederick M., *Parallel Importation: Economic and Social Welfare Dimensions* (1 June 2007). International Institute for Sustainable Development (IISD), Swiss Agency for Development and Cooperation (SDC), June 2007; FSU College of Law, Public Law Research Paper; FSU College of Law, Law, Business & Economics Paper <ssrn.com/abstract=1915395> accessed 18 March 2014

From an economical perspective, it has been suggested that parallel imports could promote fair competition preventing the pharmaceutical industry from settling medicines' prices, which is also said to represent an advantage from the public health perspective since it will enable consumers to have greater access to affordable medicines.³⁹⁸ Whether Brazil moved forward in implementing the Agreement or engaging in further commercial relations, some scholars consider that the amendments to the IP Code transformed it into one of the most advanced IP legislations within the South American continent.³⁹⁹ Nonetheless, Brazil seems to keep on tailoring their IP system, since a proposal to reform the IP law was disclosed during October 2013. This reform will be addressed within the conclusions of the research.

3.7. Summarising the Brazilian context

Thus far, Brazilian scholars continue to disagree on the overall benefits of the patent system. Some argue in favour and some against the theory suggesting that patents would boost national development.⁴⁰⁰ Regardless of the doctrinal debate, Brazil was one of the first countries to implement the TRIPS Agreement into their national IP regime among the countries analysed in this research. Given that pharmaceutical products would now receive patent protection, and that a health crisis needed to be tackled, the Brazilian legislator seemed to have also created certain mechanisms to ensure access to public health and medicines.

Admittedly, the IP law contains provisions targeting the national industry development and also to increase transfer of technology by 'foreseeing' the pharmaceutical industry to actually produce patented products in Brazil. Pharmaceutical patents are of great importance and a challenge for Brazil, since public health and access to medicines as part of the right to health are both fundamental rights.

So far, the Brazilian government has received pressure from international trading partners due to their internal policies and main objectives in guaranteeing access to medicines based on the flexibilities given by the TRIPS Agreement. Intellectual property rights are not only about economic rights in Brazil, they are also about complying with a social function that shall prevail over private interests that are contrary to the majority's interest.

Protecting public health care has required the country to withstand the heat from the pharmaceutical industry lobbying against the mechanisms envisaged within the system to serve this purpose, namely prior consent, local working requirement and compulsory licences. The Brazilian Government has undertaken serious pressures to forgo its Anuência Prévia requirement. In June 2011, Luis

³⁹⁸ Valladares Domingues, R., (ed.), *Patentes Farmacêuticas e Acesso a Medicamentos no Sistema da Organização Mundial do Comércio: A Aplicação do Acordo Trips* (Ed. Aduaneiras: São Paulo, 2005) at 79-81

³⁹⁹ See, Gomes Brunner, A., 'As Patentes Farmacêuticas e a Licença Compulsória', and Figueira Barbosa, A. L., 'Importação, Trabalho Obrigatório, Caducidade e Licença Compulsória' at 38

⁴⁰⁰ Figueira Barbosa, A.L., 'Importação, Trabalho Obrigatório, Caducidade e Licença Compulsória' at 27

Carlos Wanderley Lima,⁴⁰¹ the senior officer responsible for the prior consent policy, resigned from his post at ANVISA as a form of protest given that the Advocacia Geral da União-AGU ratified or clarified both INPI's and AVISA's competences. Hence, ANVISA since January 2011 could not keep on examining patentability requirements examined also by INPI, thereafter, voiding to a certain extent the whole prior consent concept. In this respect the Portaria n° 21 from 2013 came to play an important role in clarifying and delimitating ANVISA's competences in terms of examining the patentability requirements. However, as it will be analysed later on, the aforementioned regulation does not entirely seem to forego its intention of examining patentability requirements since it is also established that a patent claim for a pharmaceutical product is contrary to the public health when the product or processes are of interest for the national drug policy and SUS or when patentability requirements are not met. Even when the decision will justify the rationale, due to its binding character, it will be interesting to follow the interpretation given to Article 4 §1 (II) by ANVISA in the years to come.

Pharmaceutical products –especially ARV's– are part of a strategic sector for the country, and therefore, one of the ways to ensure availability and affordability is to produce them locally.⁴⁰² However, discouraging the pharmaceutical industry would pose a problem since finding a cure for certain illnesses is still an issue according to scholars, but perhaps at this point where protection is granted through a patent system the government may have to either put more pressure on the pharmaceutical companies to innovate in the required field or create new incentives to satisfy public health needs.

By creating incentives to encourage innovation within the neglected diseases field, it maybe necessary to develop a parallel system to the patent system itself. Hence, within the conclusions' chapter the hypothesis of granting out-licencing agreements for the generic industry is considered to be a viable solution to partially solve the problem of expensive medication. But whether this solution would incentive innovation it is still to be addressed.

⁴⁰¹ Coodenador da Coodenação de Propriedade Intelectual- COOPI, da Agência Nacional de Vigilância Sanitária – ANVISA, do Ministério da Saúde do Brasil.

⁴⁰² Dias Varella, M., 'Políticas Públicas para Propriedade Intelectual no Brasil' in Propriedade Intelectual e Desenvolvimento, (Ed. Aduaneiras: São Paulo, 2005) at 183

4 INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN CHILE

Chile has been praised for its economical stability and growth after going through an era of turmoil and change. In 1973 former president Salvador Allende was ousted by Augusto Pinochet, whose governmental dictatorship lasted for 17 years in what has been catalogued as a defining moment for the country's history.⁴⁰³ Pinochet's regime was not only characterised by its brutality and human rights violations, but also by paradoxical economic experiments with neoliberals that lead the country into its highest level of economic growth in 1989.⁴⁰⁴ The group of economists known as the Chicago Boys had much to do with Chile's economic success regardless of the highly controversial era. Implementing tariff reductions from 70% to 33%, cutting governmental spending by 27% and reducing fiscal deficit from 8.9% GDP to 2.9%, were among the economic measures taken to boost the national economy.⁴⁰⁵ Privatising health care, the pension system and education also played an important role in Chile's growth. Accordingly, Pinochet's regime had four stages, in which a constitutional reform took place in 1980 that allowed later on the casting of ballots that brought the era of democracy. Hence, new elected president, Patricio Aylwin, eventually ousted Pinochet in 1990.⁴⁰⁶

Nowadays, Chile is an export-based economy with an average economic growth of 5.5%, and it is also considered to be the most stable economy within the region.⁴⁰⁷ Chile managed to reduce its poverty rates from 40% to 14% between 1990 and 2006.⁴⁰⁸ Some scholars suggest that the government aggressively engaged in, and is constantly looking ahead to, concerting preferential trade agreements with not only the developed, but also neighbouring countries, that will ensure growth.⁴⁰⁹ Thus far 50 trade agreements have been negotiated by Chile,⁴¹⁰ including those with the United States of America, the European Union and Asian countries.

This chapter intends to briefly assess the origins of intellectual property protection and its constitutional approach in Chile, the challenges brought by the US-Chile Agreement related to pharmaceutical patents and the public health tradition and current developments related to pharmaceutical patents. It is important to understand the level of governmental commitment towards health care and access to medicines in a country with strong market oriented policies,

⁴⁰³ Navia, P., 'Living in Actually Existing Democracies: Democracy to the extent possible in Chile' (2010) *Latin American Research Review*, 298-335

⁴⁰⁴ Diaz, R., 'Growing Apart: Chile's Socioeconomic Divide' (2012) 32 *Harvard International Review* 2, at 7-8

⁴⁰⁵ Brender, V., 'Economic Transformation in Chile: The Formation of the Chicago Boys' (Spring 2010) 55 *The American Economist* 1, at 111-122.

⁴⁰⁶ Lahera, E., and Cabezas, M., 'Governance and Institutional Development of the Chilean Economy' (2000) 12 *Journal of International Development*, 1087-1109

⁴⁰⁷ Fischer, R., 'The expansion of Intellectual Property Rights by International Agreement: A case study comparing Chile and Australia's Bilateral FTA Negotiations with the U.S.' (Winter 2006) *Loyola of Los Angeles International and Comparative Law Review*, at 129

⁴⁰⁸ Hartwig, R., 'The Bachelet Government: Conflict and Consensus in the Post- Pinochet Chile' (2012) 87 *International Social Science Review* 1, 48-50

⁴⁰⁹ Lahera, E., et al. 'Governance and Institutional Development' at 1090

⁴¹⁰ Hartwig, R., 'The Bachelet Government' at 48

namely, identifying the strategy used to ensure protection and balance of both intellectual property right and access to medicines.

In respect to intellectual property rights, Chile has engaged in a long tradition of protection. Initially, in 1833 the Chilean Political Constitution (hereinafter the Constitution) granted protection for authors and scientists regarding productions and inventions for a period of time determined by the law in the field.⁴¹¹ Currently, IP rights receive protection in the Chilean Political Constitution's Article 19 (25) and (26) as Reformed in Ley N° 20.644 of 15 December 2012⁴¹² and also in Law No. 19.996 (hereinafter Patent Law).

On 1 December 2005 Chile issued the Patent Law that modified the previous law (Ley No. 19.039) after the Free Trade Agreement with the United States of America was signed in 2003 (hereinafter US-Chile FTA). This Agreement is known as a TRIPS plus agreement since it settles conditions far beyond the minimum standards of protection foreseen within TRIPS.⁴¹³ After this legislative reform, major concerns came along in relation to a possible conflict of competence between the Public Health Institute and national courts trying to solve controversies originating from previous products that had obtained marketing approvals authorising their commercialisation within the country. Marketing approvals *per se* became controversial as well due to the linkage between the National Health Institute and the Patent Office.

The Chilean Senate in the Bulletin No. 4180-03⁴¹⁴ highlighted the need to carefully review the aforementioned reform since neither protection for non-disclosed information in the terms established by the US-Chile FTA, namely protection of test data used in producing pharmaceuticals from being released to the public for a period of 5 years, or the above-mentioned issues were sufficiently developed within the legislation. Allegedly, Chile prior to implementing the US-Chile FTA was reluctant to execute TRIPS because these policies were deemed detrimental to the citizens' well-being⁴¹⁵ and also inconsistencies within the Patent Law available at the time challenged the compliance with TRIPS. Despite not all of these being related to patents, or the pharmaceutical industry, it is worth noting that IP enforcement in general, and effective search mechanisms to identify counterfeited goods,⁴¹⁶ in the field of copyright are challenging Chile's

⁴¹¹ Instituto Nacional de Propiedad Industrial (INAPI – Chile), 'History of the Intellectual Property System in Chile (Historia del Sistema de Propiedad Industrial)' <www.inapi.cl/index.php?option=com_content&view=article&id=34%3Ahistoria&catid=5%3Aacerca-de-inapi&Itemid=2&lang=en> accessed 3 February 2009

⁴¹² Constitución Política de La República de Chile, Senado de la República de Chile. <www.senado.cl/constitucion-politica-capitulo-i-bases-de-la-institucionalidad/prontus_senado/2012-01-16/093048.html> accessed 12 March 2013

⁴¹³ Barton, J., et al. 'Views on the Future of the Intellectual Property System, ICTSD Programme on IPR's and Sustainable Development' in *Selected Issues-ICTSD*, Brief No.1 (June 2007)

⁴¹⁴ In principle the National Health Institute seemed reluctant to acknowledge the existence of a patent previously granted for a similar product than the one intending to obtain marketing approval. See Boletín N° 4180-03, Senado de la República de Chile, Departamento de Prensa, Valparaíso, 12 Septiembre de 2006.

⁴¹⁵ Fischer, R., 'The Expansion of Intellectual Property Rights' at 129

⁴¹⁶ Woods, C., 'The United Status – Chile Free Trade Agreement: will it Stop Intellectual Property Piracy or Will American Producers be Forced to Walk the Plank' (Spring 2004) *Law and Business Review of the Americas*, at 425

performance. Hence, piracy is one major concern when it comes to intellectual property rights infringements in Chile.

It must be pointed out that the Office of the United States Trade Representatives⁴¹⁷ (hereinafter USTR) has included Chile within the “watch list” and the “priority watch list” as a result of an “Out-of-Cycle Review”⁴¹⁸ done to verify this trading partner’s commitment and compliance with the Agreement in terms of intellectual property rights.

Initially, Chile has been compelled by the United States negotiators to protect undisclosed test data from unfair commercial use, as well as unauthorised disclosure when processing marketing approvals for pharmaceutical products, to seek punishment for end-user piracy, to give a proper correlation between the patent granted and the authorisation to commercialise the product (linkage)⁴¹⁹ and to extend the time of protection due to unnecessary curtailments of time when granting patents.

According to a press release in 2007 by the USTR, Chile was highlighted as not giving priority to IPR issues since intellectual property rights were not sufficiently protected, specifically within the pharmaceutical industry. In this respect, patent owners alleged that Chile “had authorized the marketing of patent-infringing pharmaceutical products and had also failed in providing appropriate and effective mechanisms for patent holders to prevent or oppose marketing approvals for similar products.”⁴²⁰

So, Chile modified its Patent law in 2007 under Ley de Propiedad Industrial N° 20.154 (hereinafter New Patent Law) and also created the Instituto Nacional de la Propiedad Industrial- Industrial Property National Institute. This is the competent body that has dealt with intellectual property rights since 1 January 2009.⁴²¹

⁴¹⁷ The Office of the United States Trade Representative (USTR) is an agency of over 200 people, which specialises in trade issues and regions of the world. They negotiate directly with foreign governments to create trade agreements, resolve disputes and participate in global trade policy organisations. They also meet with governments, business groups, legislators and public interest groups to gather input on trade issues and explain the president’s trade policy positions. The agency was founded in 1962 and has offices in Washington, Geneva and Brussels. For further information see: The Office of the United States Trade Representative/ Who we are.

<www.ustr.gov/index.html>

⁴¹⁸ Fisher, R., ‘The Expansion of Intellectual Property Rights.’ Also see ‘2012 Special 301 Report’ *Office of the United States Trade Representatives*, at 26

<www.ustr.gov/sites/default/files/2012%20Special%20301%20Report_0.pdf> accessed 5 March 2013.

⁴¹⁹ Woods, C., ‘The United States – Chile Free Trade Agreement’ at 425-430. Also see ‘2012 Special 301 Report’ *Office of the United States Trade Representatives*, at 26.

<www.ustr.gov/sites/default/files/2012%20Special%20301%20Report_0.pdf> accessed 5 March 2013

⁴²⁰ Office of United State Trade Representative, Digital Press released 01/08/2008

<www.ustr.gov/archive/Document_Library/Press_Releases/2007/January/Schwab_Announces_Results_of_Chile_IPR_Review,_Cites_Deteriorating_Performance.html> accessed 10 March 2013

⁴²¹ Instituto de la Propiedad Industrial de Chile (INAPI), Historia del sistema de Propiedad Industrial

Although improving IPR enforcement is among Chile's priorities, public health and access to medicines are priorities as well. Hence, promoting competition and the issue of affordable medicines will also be analysed within the chapter. On the one hand, price competition seems to be an adequate solution to lower medicine prices. However, it has been suggested that generic producers are also making significant profits out of highly pricing their products, which contradicts the principle of "affordable medicines."⁴²²

4.1. Chilean Patent System and Grant Procedure

Chile has offered protection for intellectual property rights since 1833, but in the past the protection was not as well defined as later on in 1980 when the new Chilean Political Constitution was reformed. Chile also ratified the Paris Convention for the Protection of Industrial Property on 14 November 1991.⁴²³ However, protection for pharmaceutical products was not available until after Chile joined the World Trade Organization (WTO) and had to comply with the new standards of protection settled in light of the TRIPS agreements.

Before analysing the patent system and the implementation of TRIPS in Chile it is important to highlight that the Treaties, Agreements and Conventions negotiated by the President require parliamentary approval before they can be effectively executed.⁴²⁴

The Intellectual Property Law N° 19.039 modernised the Chilean intellectual property system, providing adequate protection for inventions and scientists. Furthermore, the law provides precise definitions for the concepts of inventions and patents,⁴²⁵ patentability requirements⁴²⁶ and terms and conditions related to

<www.inapi.cl/index.php?option=com_content&view=article&id=34%3Ahistoria&catid=5%3Aacerca-de-inapi&Itemid=2&lang=en> accessed 5 March 2013

⁴²² Dumas Rossi, E., 'El Dilema de Heinz en el contexto de las Patentes Farmacéuticas' Potificia Universidad Católica de Chile (2007). In this paper, the author addresses the question of who really has the responsibility for providing adequate access to affordable medicines in Chile. The Government, the industry or both?

<www.centrocardiologico.cl/El%20dilema%20de%20Heintz.pdf> accessed 10 March 2013

⁴²³ Decreto N° 425, Promulga la aprobación del Convenio de París para la Protección de la Propiedad Industrial, Promulgado en fecha 08 de Abril de 1991 y Publicado el 30 de Septiembre de 1991 <www.leychile.cl/Navegar?idNorma=13255&idParte=&idVersion=1991-09-30> accessed 10 March 2013

⁴²⁴ Article 32 (15) and Article 54 (1) from Constitución de Política de la República de Chile, Texto Refundido, Coordinado y Sistematizado de la Constitución de la República de Chile, Ministerio Secretaría General de la Presidencia, Decreto N° 100, Promulgado en Fecha 22 Septiembre de 2005, y publicado en fecha 17 de Septiembre de 2005. (hereinafter Constitution of Chile)

⁴²⁵ Vrsalovic, I., 'Fundamentos, Conceptos y Definiciones sobre la Propiedad Industrial y la Protección Jurídica de los Derechos de Inventor' (Abril, 1993) *La Propiedad Industrial y sus Proyección as los Productos Farmacéuticos*, at 21. And See also Ley N° 19.996. CHILE. Propiedad Industrial. Fija Texto Refundido, Coordinado y Sistemaitzado de la Ley de Propierdad Industrial. Ministerio de Economía, Fomento y Reconstrucción. Santiago de Chile, 9 de Marzo de 2006. (hereinafter Patent Law N° 19.996) Article 31 "...**invention**... shall mean any solution to a technical problem arising in an industrial concern. An invention may be or relate to a product or process.... "**patent**" shall mean the exclusive right granted by the State for the protection of an invention. The effects, obligations and limitations embodied in the patent shall be determined by this Law."

compulsory licences⁴²⁷ and marketing approvals (or sanitary registrations as defined by the legislation).⁴²⁸

The Instituto Nacional de Propiedad Industrial – National Institute for Industrial Property (hereinafter INAPI) is the competent body to grant patent rights and to deal with intellectual property rights in Chile.⁴²⁹ Even though this is an independent agency, INAPI observance is under the Ministerio de Economía, Fomento y Reconstrucción – Ministry of Economics, Development and Reconstruction. Previously, the Departamento de Propiedad Industrial – Department for Industrial Property had as its main attributions processing applications for industrial property protection, solving cases related to acceptance or rejection of IPR's' and managing other general aspects. Whereas the new patent office is not limited to manage IPRs, since their attributions extend to analysing possible international treaties or agreements that Chile could become part from.⁴³⁰

This part of the chapter intends to analyse the patent grant procedures within the legislation in light of the amendments to comply with both TRIPS and the US-Chile FTA. The Chilean Patent law begins by establishing its competence to review and registered IP rights. Accordingly, patent applications, before being accepted for registration shall pass a formal or preliminary exam that is designed to verify if the application fulfils the requirements given by law.⁴³¹

Article 4° from the Patent Law N° 19.996 mandates the publication of an extract of the patent application within the Official Journal once the application has been accepted for processing by INAPI, which only occurs after the preliminary examination. This provision is complemented by Article 5 from the Ley N° 19.039 that grants 60 days from the filing date for INAPI to comply with mandatory publication.

Following the publication, the interested parties may present opposition before INAPI in a period of forty-five (45) days from the time of the publication.⁴³² After this initial verification phase expires, the patent office will perform the substantial examination as requested by the parties,⁴³³ giving INAPI 60 days to return the report to the experts.⁴³⁴

An interesting issue within the Chilean IP Law is the fact that the chapter related to patents is named “De las Invenciones” (Inventions) instead of “Patents” as

Translation by WIPO. Highlight and modifications made by the author

<www.wipo.int/edocs/lexdocs/laws/en/cl/clo46en.pdf> accessed 10 March 2013

⁴²⁶ See Articles 33, 35 and 36 from Patent Law N° 19.996

⁴²⁷ See Article 51 from Patent Law N° 19.996

⁴²⁸ See Título VIII, Párrafo 2°, Articles 89 -91 from Patent Law N° 19.996

⁴²⁹ INAPI was created by Ley N° 20.254 published within Diario Oficial de la República de Chile N° 39.036 dated 14 April 2008.

⁴³⁰ See Article 3 from Ley N° 20.254, published in Gaceta Oficial N° 39.036

⁴³¹ Article 45 from Patent Law N° 19.996 “The patent application shall be accompanied by the following documents: an abstract of the invention; a description of the invention; a claims sheet; drawings of the invention where appropriate.”

⁴³² Article 5 from Ley N° 19.996

⁴³³ Article 6 from Ley N° 19.996

⁴³⁴ Article 7 from Ley N° 19.996

generally found in other legislations. Inventions are defined by the law, “as any solution to technical problem arising from an industrial concern, which can be related to a product or process.”⁴³⁵

Articles 33, 35 and 36 from the Patent Law N° 19.996 provide definitions as to what is to be understood as novelty, innovation and industrial applicability within the Chilean context. In between these definitions, the legislation approaches the priority right given to foreign applications. Without elaborating too much on the case, the legislator limits it to granting twelve (12) months from the date of application abroad to submit the claim in Chile.⁴³⁶

Both prohibitions and non-patentable subject matters are settled within Article 37 of the IP Law. Among these are second medical uses, discoveries, scientific theories and mathematical methods.⁴³⁷ Any patents that go against public order or public health are prohibited. In terms of prohibitions the legislation is specific in highlighting the possibility of preventing certain inventions in being commercialised within the country due to public health or national security reasons or to preserve the environment.⁴³⁸

Only three scenarios are foreseen by the legislation to void patents in Chile, namely when the claimant of the patent rights is not the real inventor, when the patent grant was based on misleading or deficient examination of content (or expert reports as assessed by the Law) and when the patent was granted contrary to patentability requirements which constitute a cause for invalidating the patent.⁴³⁹

Compulsory licences are also envisaged within the legislation. Despite Chile being a Paris Convention Member, no provision expressly settling the local working requirement is found within the legislation. Thus, compulsory licences are mainly to correct anti-competitive practices and to solve public health emergencies.⁴⁴⁰

⁴³⁵ Article 13 from Ley N° 19.996 English version provided by WIPO. Law No. 19.039 on Industrial Property (Consolidated Law approved by Decree-Law No. 3)

⁴³⁶ Article 34 from Ley N° 19.996

⁴³⁷ Second uses are initially forbidden. However, the same article highlights that if a second use fulfills patentability requirements established by Law then it could obtain patent protection. Article 37 from Patent Law N° 19.996

⁴³⁸ See Article 37 from Patent Law N° 19.996

⁴³⁹ Article 50 from Patent Law N° 19.996 “A patent may be invalidated on any of the following grounds: (a) where the person who obtained the patent is neither the inventor nor his licensee; (b) where the patent has been granted on the basis of erroneous or manifestly deficient examiners’ reports; (c) where the title has been granted in contravention of the rules of patentability and related requirements, as provided for in this Law. A patent for an invention may be the subject of an invalidation action during a period of five years, beginning from the date of registration.”

⁴⁴⁰ Article 51 from Patent Law N° 19.996 “Nonvoluntary licenses may be granted in the following cases: (1) where the holder of a patent has engaged in conduct or practices declared contrary to free competition, directly related to the use or exploitation of the patent in question, according to a final decision by the Antitrust Tribunal; (2) where the granting of such licenses may be justified for reasons of public health, national security, noncommercial public use or on other extremely urgent grounds declared by the competent authority; (3) where the purpose of the nonvoluntary license is the exploitation of a subsequent patent that could not be worked without infringing a previous patent.”

One particular point brought by this IP Law is the protection of undisclosed information, as Article 89 specifically delimits the need to safeguard these kinds of data from third parties when applying for a marketing approval to commercialise *known products*. This Article also forbids the National Health institute from using the information available in the files related to that product, as a basis to approve marketing approvals.⁴⁴¹ Certain exceptions to this rule also apply, mainly related to public health needs.

An interesting fact denoting Chile's evolution on industrial property matters is the creation of an Industrial Property Court where issues related to these kinds of rights must be heard before passing over to a higher judicial and civil instance. The Chilean law is very clear in delimiting functions, jurisdiction and the competence for this Court.

4.2. U.S. – Chile Free Trade Agreement: Implementing Higher Standards of Protection*

Thus far Chile has signed three free trade agreements and one association agreement where intellectual property right issues are discussed and negotiated. Among the most important ones are the Chile- Korea, Chile – USA, Chile - Mexico⁴⁴² and Chile-E.U⁴⁴³

⁴⁴¹ Article 89 from Patent Law N° 19.996 “Where the Instituto de Salud Pública (ISP – Public Health Agency)... requires the submission of proof or other undisclosed information concerning the safety and effectiveness of a pharmaceutical product or agricultural chemical that utilizes a new chemical entity that has not been previously approved by the competent authority, such information shall be considered confidential pursuant to the regulations in force.

The nature of nondisclosure shall be deemed satisfied if the data have been subject to reasonable measures to keep it undisclosed and they are not generally known to or easily accessed by persons within the circles in which the type of information in question is normally used.

The competent authority may not disclose or utilize such data to grant a health registration or authorization to someone who does not have the permission of the holder thereof, for a period of five years for pharmaceutical products and 10 years for agricultural chemicals, beginning from the first health registration or authorization granted by ISP or SAG, as the case may be.

In order to enjoy protection under this Article, the nature of non-disclosure of such data shall be expressly stipulated in the health registration or authorization application.”

* Substantive parts from the analysis of the pharmaceutical linkage carried out within this heading were already published by the Doctoral student in Cadillo Chandler, D.M., ‘Pharmaceutical Patents and Marketing Approvals within the U.S. –Chile Free Trade Agreement Context: A brief Analysis’ in *In Search of New IPR regimes* (IPR University Center, Helsinki - 2010) 201-218

⁴⁴² Palma Oyedo, P., ‘Los Tratados de Libre Comercio y los Medicamentos’ (2004) *Medicamentos y Tratados de Libre Comercio*, at 25

⁴⁴³ Association Agreement between the European Union and Chile. “Article 2. 1 This Agreement establishes a Political and Economic Association between the Parties, based on reciprocity, common interest and on the deepening of the relationship in all areas of application. 2. The Association is a process that will lead to a growing relationship and cooperation between the Parties structured around the bodies created in this Agreement. 3. This Agreement covers in particular the political, commercial, economic and financial, scientific, technological, social, cultural and cooperation fields. It may be extended to other areas to be agreed upon by the Parties” <www.sice.oas.org/Trade/chieu_e/Chieu1_e.asp> accessed 10 April 2013

The Free Trade Agreement between Chile and the United States (hereinafter U.S.-Chile FTA) received the Congress's approval on Decree N° 312 in 2003 by the Ministry of Foreign Relations.⁴⁴⁴

It has been highlighted that Chile's major challenge is the full implementation of the FTA. Therefore, preventing patent infringements and solving the alleged linkage unconstitutionality are of great importance so as to comply with the signed agreement.⁴⁴⁵ The problem with the linkage regards to possible patent infringements by third parties due to a legislative reform post U.S.-Chile FTA that does not legitimate the linkage.

Allegedly there is an increasing trend in qualifying bilateral agreements signed with industrialised countries like the U.S., as TRIPS plus agreements are generally a consequence from a bargain for market access.⁴⁴⁶ Professor José Manuel Cousiño from the Chilean Chamber for the Pharmaceutical Industry does not find the agreement to be very different from the TRIPS Agreement previously ratified by Chile when becoming a World Trade Organization Member State, and the fact that a country implements higher standards of protection within a free trade agreement does not make it a TRIP plus agreement. Moreover, attention has also been drawn to the fact that Chile will be a different country in 10 years due to a greater access into international markets.⁴⁴⁷ The fact that these agreements involve higher intellectual property standards is causing great concern and has led to a part of the doctrine to suggest that the agreement ratified by Chile with the U.S. was a bad deal.⁴⁴⁸

Within the U.S.-Chile FTA context there are some other relevant provisions regarding intellectual property rights but for the purpose and clarity of this study mainly those related to regulated products or pharmaceutical products will be analysed. In the light of the U.S.-Chile FTA not only pharmaceutical products are regulated but also agricultural products, identifying these within the agreement as *regulated products*. It must be highlighted and, as mentioned before, that this is not the first time that Chile negotiated higher standards of protection through a free trade agreement with another trading partner. In 1999 Chile signed an Economic Complementation Agreement with Mexico⁴⁴⁹, where among many

⁴⁴⁴ Gobierno de la República de Chile, Decreto N° 312 del 01 de Diciembre de 2003, Publicado en Diario Oficial el 31 de Diciembre de 2003

<www.bcn.cl/lc/tinterna/tratados_pdf/tratado_vallyo72.pdf> English version<www.ustr.gov/sites/default/files/uploads/agreements/fta/chile/asset_upload_file941_4019.pdf> accessed 10 April 2013

⁴⁴⁵ Palma Oyedo, J., 'Los Tratados de Libre Comercio y los Medicamentos' at 25

⁴⁴⁶ Ho, C., 'A New World for Addressing Patenting Rights and Public Health' (2007)82 Chicago Kent Law Review 3 <www.cklawreview.com/wp-content/uploads/vol82no3/Ho.pdf>

⁴⁴⁷ Cousiño, J.M., 'Tratados de Libre Comercio y sus Efectos Sobre el Mercado Farmacéutico Chileno' (2004) Medicamentos y Tratados de Libre Comercio, at 41 - 49. Original text in Spanish, part of the reference is also corroborated in an interview held in May 2009 with Professor Cousiño.

⁴⁴⁸ Correa, C., 'Mal Negocio de Chile con Estados Unidos' in *Le monde Diplomatique*, March 2004. <www.insumisos.com/diplo/NODE/156.HTM> Original text in Spanish. English translation available at <www.qiap.ca>

⁴⁴⁹ Levis, M., 'Role, Perspectives and Challenges of the Generic Pharmaceutical Industry in Latin America, ICTSD – UNCTAD' in *Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines*, Bellagio, 12-16 Oct. 04, at 1-9. Free Trade Agreements between the United

other things, intellectual property rights were negotiated⁴⁵⁰ particularly in the field of trademarks.

Another important issue is regards whether or not Chile resigned the use of the flexibilities available in the TRIPs Agreement by virtue of the bilateral agreement signed with the United States. It has been suggested that this FTA will be a barrier for Chiles' public health due to the impossibility of legally introducing generics onto the market based on patent availability; hence Chile would be giving up many of the flexibilities previously granted by the TRIPS.

Article 17.1.5 clause on applicability, expressly points out that "nothing in the Chapter concerning intellectual property rights shall derogate ... the obligations and rights of one party in respect to the other by virtue of the TRIPS Agreement"⁴⁵¹ and also the Chilean legislation provides the conditions and terms for enacting a compulsory licence. Reading both the Spanish and the English versions of the Agreement brings to forefront the rationale over the impossibility in making use of the flexibilities by Chile. Initially these flexibilities were granted by the TRIPS Agreement and the DOHA declaration on the TRIPS Agreement and Public Health,⁴⁵² but nevertheless within the context of the English version of the clause related to the exception it suggests the existence of certain discrepancies, giving perhaps some space for confusion, while the Spanish version is crystal clear.

The US-Chile FTA covers a great variety of topics related to trade between the two contracting parties, and this is deemed beneficial for the Chilean economy due to its international exposure.⁴⁵³ Some have even described the FTA as a bad deal by mainly emphasising the higher levels of protection for pharmaceutical products, highlighting the negative impact on the access to medicines as mentioned previously. In this respect, access to medicines was seen as endangered due to a possible extension on the length for patent protection, delaying the entry of generics into the market.⁴⁵⁴ Moreover, a special concern exists over the clauses regarding data protection, linkage, extension of protection and TRIP Flexibilities. Attention must be drawn to the fact that most of the doctrine against the FTA was written in 2004, and Chile managed to reform the intellectual property legislation according with the TRIPS almost 5 years after the FTA was ratified.

States and Developing countries. Negotiating further intellectual property protection templates which most likely go beyond the general TRIPS Agreement

⁴⁵⁰ Roffe, P., 'Bilateral agreements and a TRIPS-plus world: the Chile-USA Free Trade Agreement' (October 2004) Quaker International Affairs Programme - TRIPS Issue Paper 4

⁴⁵¹ Free Trade Agreement between Chile and USA. Article 17.1.5. " Nothing in this Chapter concerning intellectual property rights shall derogate from the obligations and rights of one Party with respect to the other by virtue of the TRIPS Agreement or multilateral intellectual property agreements concluded or administered under the auspices of the World Intellectual Property Organization (WIPO)..."

⁴⁵² WT/MIN(01)/DEC/2, 20th November 2001 "Declaration on the TRIPS Agreement and Public Health". The Doha Declaration recognises the need of least developed and developing countries with no manufacturing capability and the need to protect public health beyond the previous negotiated within the TRIPS Agreement, therefore granting certain flexibilities and freedom for countries to supply internal market needs.

⁴⁵³ Cousiño, J.M., 'Tratados de Libre Comercio y sus Efectos Sobre el Mercado Farmacéutico Chileno' (2004) *Medicamentos y Tratados de Libre Comercio*, at 41 - 49. Original text in Spanish

⁴⁵⁴ Idem

Another relevant argument stressed during 2004 was that nothing within the Chilean legislation at that time stated anything related to compulsory licences and parallel imports, but by 2006 when the Patent Law N°19.039 came into force posterior to the FTA, Articles 51(2), 51 bis A, and Article 70 from the patent law's Regulation, the Chilean government clearly foresaw a compulsory licence regime.⁴⁵⁵ As with to parallel imports, the only way for an exemption to be available may be through Sanitary Code Articles 100 and 102, where the first Article points out the creation of a National Chart of Indispensable Medicines (Formulario Nacional de Medicamentos), and the second Article establishes within the second paragraph that no marketing approval or sanitary permit is needed in cases of medical urgency.⁴⁵⁶ With the creation of a National Chart of Indispensable Medicines, the Chilean Government makes sure to determine which pharmaceutical products are not patentable subjects and those that could be required with no further notice to patent owners due to a national emergency or medical urgency.⁴⁵⁷

⁴⁵⁵ Ley N° 19.039, Article 51 “the decision on a compulsory licence will proceed within the following cases: ... 3) due to public health reasons, national security, non-commercial public use or national emergency or other extreme emergency declared by the competent authority, justifies the granting of those licenses...” Article 51 bis A “the compulsory licence applicant will have to provide documentation enough to justify his previous request to the patent owner for the use of a patent licence and that this one was not possible to be achieved within reasonable terms, conditions and time. This requirement will not proceed due to the previously established by this law Articles’ 51.2. Nor will be required in cases where the compulsory licences’ object is to sanction anti competitive practices”

<www.leychile.cl/Navegar?idNorma=250708&idVersion=2007-01-26>

⁴⁵⁶ Sanitary Code (Código Sanitario) Decree N° 725/67 later on modified by Ley N° 20.308 published by Official Diary 27.12.2008. Article 100 “The Ministry of Health, previous technical report from its Technical Regulation Units, will approve a National Chart of Indispensable Medicines to supply the country's needs. This Chart will specify the pharmaceutical form and dosage of the pharmaceutical product and it will also describe the use, limitations and side effects of those products...” Article 102 “... no pharmaceutical product shall be commercialised or distributed in the country without previous registration at the National Health Institute... Although the sanitary authority is able to authorise the provisional distribution and commercialisation of such a product for medical urgency reasons” Original text in Spanish translations by the author. Para concretar una Reforma de salud global, en el ámbito del acceso a medicamentos seguros, efectivos y de calidad se espera la participación y el compromiso de los fabricantes/importadores de medicamentos en la producción/importación de éstos bajo denominación genérica. Que el país cuente con medicamentos bajo denominación genérica implica la factibilidad de ampliar el acceso a las terapias farmacológicas incluidas en el AUG.

⁴⁵⁷ Decreto 194 enacted on 26.08.2005, published on Diario Oficial 10.03.2006. This Official Decree settles the existence of the National Chart of Indispensable Medicines (Formulario Nacional de Medicamentos). Decreto 264 enacted on 10.12.2003 and published on Diario Oficial on 16.03.2004. This Official Decree is the Complementary Regulation to the Decree 194 and the Regulation settles the parameters to the National Chart of Indispensable Medicines

4.2.1. Linkage and Sanitary Permits⁴⁵⁸

The existing link between the patent and the sanitary permit established in Article 17.10.2 has created controversy among the Chilean legislative community.

“Article 17.10.2. With respect to pharmaceutical products that are subject to a patent, each Party shall:

(a) make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;

(b) make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent; and

(c) not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner”⁴⁵⁹

This Article expressly foresees the contracting parties’ duty in preventing third parties commercialising an already patented product by a third party different than the owner without its consent. Although Article 17.9.4 points out the duties of the parties when importing or exporting, this procedure or linkage is developed through Article 17.9 and 17.10, where not only the duty to provide information to patent owners is settled but also the duty to deny sanitary permits on basis of the existence of an available patent for that pharmaceutical product.

A report from the United Nations Development Program in 2005 highlighted that in most countries pharmaceutical patents and their registrations to commercialise e status are two separate issues, thus also assessed by two different bodies or institutions.⁴⁶⁰ In Chile the Instituto Nacional de la Propiedad Industrial – *INAPI* (Patent Office) is the body responsible for evaluating if the pharmaceutical product or process complies with the patent requisites, and the Instituto Nacional de Salud Pública – *ISP* (National Health Institute) is the one responsible for assessing on whether or not the pharmaceutical is of sufficient quality, safe and effective to be granted a marketing approval.⁴⁶¹

The challenge with the linkage regards the functions originally given to the ISP by the Ministry of Health, which according to its own regulation’s Article 4(b) is

⁴⁵⁸ The term “sanitary permit” is a direct translation from the Spanish “permisos sanitarios”. As the discussion will later highlight, this concept is used as a marketing approval, commercial authorisation and formal registration synonyms, which are a formality required prior to the commercialisation of a pharmaceutical product. This sanitary permit is to be granted by the Chilean National Health Institute

⁴⁵⁹Article 17.10.2 Free Trade Agreement US-Chile. This Article brings to the spotlight three different situations that are seen as higher standards than the ones already established by the TRIPS Agreement.

⁴⁶⁰ Ruth Mayne; “Regionalism, Bilateralism, and “TRIPS Plus” Agreements: The Threat to Developing Countries” in Human Development Report Office Occasional Paper, Human Development Report 2005, UNDP 2005/18.

⁴⁶¹ Reglamento del Instituto de Salud Pública. Article 4. “The National Health Institute functions will be: b.) To perform the activities related to drug quality control, medical food use and other products subject to health controls, which include the following functions:”“3: control the conditions, exports, manufacturing process, distribution and commercialisation ... of those product according with the regulations” Original text in Spanish, translation by the author.

entitled to control quality and effectiveness of those products⁴⁶² regulated under the National Control System for Pharmaceutical Products Regulation.⁴⁶³ Allegedly, the FTA could be creating a new function for the ISP through Article 17.10.2.c when stressing the duty to deny a sanitary permit.

Article 17.10.2. Each party shall: (c) not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner⁴⁶⁴

Accordingly, as a new procedure in the Chilean legislation to protect pharmaceutical products, the fact that the legislation per se does not define what linkage means and the ISP's refusal in recognising their duty to provide marketing approvals even when its own legislation and regulation provided so has divided scholars in Chile. Thus far, linkage could be understood as the available connection within the sanitary permit and the patent before a pharmaceutical product could be commercialised in a specific market. And this is produced by the connection that exists between the authorities granting marketing approvals and the one granting patents. Secondly, within the context of the FTA as pointed out above, the authority granting the sanitary permit shall "not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner"⁴⁶⁵ but in so far only one Court ruling stated the duties and the correct interpretation to the pharmaceutical legislation⁴⁶⁶, which later on was contradicted by another ruling.

Interestingly enough the ISP was an object of controversy even before the FTA was signed. As early as 2001 the ISP was sued in court by non-governmental organisations looking forward at the unconstitutionality of a marketing approval granted by this institution to commercialise Postinal.⁴⁶⁷ Another interesting fact related to these sanitary permits is the reference made to "marketing approvals" within the frame of the legislation before been reformed after the U.S.-Chile FTA.⁴⁶⁸

⁴⁶² See Decreto 194 enacted on 26.08.2005

⁴⁶³ National Control System for Pharmaceuticals, Food and Medical Use Cosmetics Regulation (Reglamento del Sistema Nacional De control de Productos Farmacéuticos, alimentos de Uso Médico y Cosméticos, D.S 1876/1995)

⁴⁶⁴ Correa, C., 'Mal Negocio de Chile con Estados Unidos'

⁴⁶⁵ Mayne, R., 'Regionalism, Bilateralism, and "TRIPS plus" Agreements'

⁴⁶⁶ 30 Juzgado Civil de Santiago, Rol C-6613-2003, Porzio Bozzolo (Pfizer Chile S.A.) Vs. Ministerio/ Instituto de Salud Pública (2006). This case took around three years in court before been decided, but so far this is one of the few ruling where a Chilean court has really analysed in depth the intellectual property and pharmaceutical legislation with regard to a sanitary permit (marketing approval)

⁴⁶⁷ Postinal is the pharmaceutical product manufactured on basis of Levonorgestrel. This is a drug according to the Chilean Supreme Court's ruling of 30 August 2001, Rol N°2186-2001 which is deemed unconstitutional due to its abortive effects. As will be discussed below, this Court ruling voided the sanitary permits granted to commercialise and distribute the product in the country. Original text in Spanish.

⁴⁶⁸ National Control System for Pharmaceuticals, Food and Medical Use Cosmetics Regulation (Reglamento del Sistema Nacional De control de Productos Farmacéuticos, alimentos de Uso Médico y Cosméticos, D.S 1876/1995) Article 37: "the application for marketing registration to commercialize (marketing approval) or to distribute a pharmaceutical product imported or manufactured in the country, the applicant shall present before the ISP, in pre approved forms the ones that will be registered by the person or its legal representative" Translation by the author,

In terms of Article 17(10)(c) from the FTA, regarding the denial of marketing approvals it is pointed out that part (b) reads, "... Each Party shall ... make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent...".⁴⁶⁹ This became controversial, but it did not seem to be different from what was already stated by the Resolution N°14 in relation to the sanitary permits and patents from the ISP. Within the Resolution parts 7 and 8, patent holders were to be informed about third parties requesting marketing approvals for similar products to the ones already patented.⁴⁷⁰

In the light of the aforementioned Article's part (b), Chile should not only provide the information to patent holders, but the ISP should also have access to the information on whether or not there is a patent pending or expired. Currently this institution stated its lack of competence to access that kind of information through Resolution No. 005572, where the ISP delimitates its attributions in not interfering with patent rights.⁴⁷¹ Besides their incompetence over intellectual property matters, the ISP on several occasions has made obvious their incapability to grant marketing approvals, since only sanitary registrations are to be granted which under any circumstances can be acknowledged as an authorisation to commercialise in according with the Republic of Chile Comptroller's Office⁴⁷² (Contraloría General de la República de Chile) in 2002.

bolded and in cursive to highlight a point by the author. The D.S 1876/1995 was modified by Dto. 245/03, and this reform made reference in Article 37 to a plain registration and not a marketing approval as will later on be discussed.

⁴⁶⁹ Ibid

⁴⁷⁰ Instituto de Salud Pública de la República de Chile, Circular No. 14, Santiago 28 de Noviembre de 2001. Part 7: "in order to provide transparency to the rights and expectations of the diverse right holders, the institute shall provide information regarding patent certificates of products with similar composition, of those applications to integrate patent certificates into the registry system, by providing all the relevant documents". Part 8: "In the same respect this Institution will provide information to right holders which are also patent owners about posterior applications to register a product with similar composition as the one previously registered by them" Original text in Spanish, translations by the author. This Circular No. 14 (Resolution No.14 was modified later on by Resolution No.005572 in July 12th 2004)

⁴⁷¹ Instituto de Salud Pública de la República de Chile, Resolución No. 005572, Santiago 12 de Julio de 2004. Taking into consideration: "First: considering that the ISP due to its juridical nature, attributions and functions lacks competence to solve conflicts derived from rights and privileges granted by the Law No. 19.039 in relation to patents" "Second: nevertheless it is necessary to provide guarantees enough to every counterpart, as in regards of patents related to pharmaceutical products sanitary permits, as to enable them in taking the matter to competent judicial and administrative instances to solve those conflicts they may be part of..." "Third: the previous objective is granted by allowing the interested parties to have access to the information related to applications or requests for sanitary permits for pharmaceutical products, so as the resolutions granting the permits..." Decides to: "1st: ...publish a list with the information related to sanitary permits applications for pharmaceutical products, providing the relevant information about the applicants and product..." This Resolution leaves in the right holder's hands the duty to look after their own interests by periodically checking for similar products as theirs, because the ISP will not inform them about any application or deny a similar marketing approval for the same product. Original text in Spanish, translations by the author.

⁴⁷² The General Comptroller Office of the Republic of Chile (CGR) is in charge of controlling the State's Administration; a task assigned it in the Political Constitution. It is independent from the Executive Branch and other government entities and essentially ensures that the acts of the State Administration are legal. It is not subordinate or overseen by the Executive Branch or Congress.

By 2 September 2002 the Quinta Sala from the I Corte de Apelaciones (I Court of Appeals, Fifth Chamber) acknowledged Pfizer Chile S.A a motion to prevent the marketing approvals or sanitary permits for second uses to Laboratorios Recalcine S.A by the ISP for the same pharmaceutical product (Ziprasidona) and the procedure to obtain Ziprasidona.⁴⁷³ Pfizer Chile S.A sought to prevent the granting of those sanitary permits on basis of a patent infringement, but the Court of Appeals sentenced Pfizer to cover the cost of the trial while at the same time legitimised Recalcines' sanitary permits on the basis of the ISP's lack of competence to rule over conflicts related to patent rights. Interestingly, the Court of Appeals dealt with the issue, and regardless of what was established in the legislation and the ISP's Resolution N°14, the Court ruled that the ISP had no competence what-so-ever to either deny a marketing approval or to acknowledge any right derived from a patent.

Beyond pointing out the fact that the ISP has been under the microscope for a while, these lines intend to draw attention to the fact that some of the challenges attributed to the FTA already existed even before its ratification. Therefore, the necessity to analyse the most relevant cases available were not only contradictions between the Court rulings over the matter, but also the ISP itself and the legislation. The fact that the ISP grants a sanitary permit albeit authorisation to commercialise, lies on Article 102 from the Sanitary Code and Article 11 from the Reglamento Nacional de Control Sanitario (National Regulation on Sanitary Control), where both Articles correlate with each other by stating that no pharmaceutical product shall be sold in the country if a sanitary permit has not been previously granted.⁴⁷⁴ So if a pharmaceutical product cannot be sold without this sanitary permit, is it not then possible to assume that this sanitary permit is actually a marketing approval or an authorisation to commercialise?

The task of the CGR is by far oversight. It is charged with protecting the principle of legality, i.e. confirming that the organs of the State's Administration act according to their attributions following the procedures contemplated in the law.

<www.contraloria.cl/NewPortal2/portal2/appmanager/portalCGR/eng?_nfpb=true&_pageLabel=ENG_WhoWeAreCGR_v2>

Contraloría General de la República de Chile. Dictamen 051760N02 from 17.12.2002. Cámara de la Industria Farmacéutica vs. ASILFA and ISP

⁴⁷³ *Ziprasidona (Ziprasidone) is a neuropharmacologic used for schizophrenia and to prevent psychotic relapses commercialised and manufactured in Chile by Pfizer Chile S.A. The procedure is protected by the patent No. 36.533, and the product is protected by the patent No. 41.031. I Corte de Apelaciones de Santiago, Rol. 3747-2002, Pfizer Chile S.A. Vs. Laboratorios Recalcine S.A. and the ISP (2002)*

⁴⁷⁴ Sanitary Code (Código Sanitario) Decree N° 725/67 later on modified by Ley N° 20.308 published by Official Diary 27.12.2008; Article 102: "No pharmaceutical product ...shall be commercialized or distributed in the country without previous registration at the National Health Institute..."; National Control System for Pharmaceuticals, Food and Medical Use Cosmetics Regulation (Reglamento del Sistema Nacional de control de Productos Farmacéuticos, alimentos de Uso Médico y Cosméticos, D.S 1876/1995) Article 11: "Every product imported or manufactured in the country, before been distributed or sold in the country, shall have a sanitary permit granted according the terms and conditions established by this regulation..."

4.2.2. Relevant case law:

I Court of appeals, Republic of Chile, Rol 3747-2002⁴⁷⁵

In this case, Pfizer sought an injunction to prevent the ISP in granting the sanitary permits in favour of Laboratorio Recalcine, which would have had allowed them to commercialise the generic version of Pfizer's product without their consent (original owner). In doing so, the plaintiff also sought to delimit the ISP's competences and also the National Health Institute sought, at the same time, to clarify its position in terms of marketing approvals.

The Court of Appeals ruled within the Rol. 3747-2002, that the National Health Institute lacks competence to solve any controversy derived from a patent and therefore this institution attribution only allows pharmaceutical product registrations to thereafter grant a sanitary permit. The original motion for an injunction to prevent the granting of a sanitary permit deviated into a conflict of pure intellectual property between the parties in question.

During the proceedings the Court understood the matter as a conflict derived from an intellectual property privilege granted to the owner by the Law N° 19.039 and therefore this conflict accordingly should have been presented before the INAPI Chief of Department whom would have had to decide. Otherwise, a Civil Court should have solved the case. Moreover, the court stated that this institution has nothing to do with a patent right or the ability to determine the scope of patent protection granted and thereafter if a sanitary permit was requested by a third party the ISP had to limit itself in only verifying exclusively that the requirements were fulfilled. Another relevant argument used by Pfizer, and later on used against the company, was the fact that the company alleges to have accidentally learned about Laboratorio's Recalcine request before the ISP for the approval of the permits in question. Later on the court, due to the ISP's allegation, dismissed the previous argument over the matter, which basically suggested their good diligence in making the plaintiff aware of the situation when the institution submitted a letter of notification that was not accepted.⁴⁷⁶ The last argument draws attention to the duty of the ISP in making available to patent owners the identity of third parties requesting marketing approvals during the term of the patent, as the U.S.-Chile FTA Article 17(10) b suggested a year after this ruling.

General Comptroller Office, Republic of Chile Dict. 051760No2⁴⁷⁷

Perhaps the previous case was reinforced by the comptroller's office ruling over the Chilean Pharmaceutical Chamber's claim to clarify the National Health Institute's real attributions, as this was granting sanitary permits for copies of pharmaceutical products with a valid patent. In this case the Asociación

⁴⁷⁵ Quinta Sala, I Corte de Apelaciones de Santiago, Rol No.3747-2002, Pfizer Chile S.A. Vs. Laboratorio Recalcine S.A./ Instituto Nacional de Salud (Ziprasidona case)

⁴⁷⁶ Id. Ut Supra 38

⁴⁷⁷ Contraloría General de la República de Chile, Dictamen No. 51760 de fecha 17.12.2002, Cámara de la Industria Farmacéutica Vs. ASILFA/ISP

Industrial de Laboratorios Farmacéuticos Chilenos A.G. (hereinafter ASILFA)⁴⁷⁸ sought for the Comptroller to clarify the ISP and to acknowledge that its main responsibility did not regard granting the sanitary permits to those products that fulfil the legal requirements, but also to verify the existence of patent rights.

After an extensive analysis, the Comptroller's Office dismissed the Pharmaceutical Chambers petition dictating that the ISP was not legally attributed to deny a sanitary permit neither on the basis of a valid patent nor to analyse the privileges deriving from the Law No. 19.030 (patent law). And therefore the parties shall present in court when fears over the vulnerability of their rights where plausible.

It is important to highlight that Resolution No.14 was still valid and therefore the ISP had the duty to inform patent owners about third parties' applications to obtain marketing approvals or sanitary permits to commercialise similar products without their consent.

20° Civil Court of Santiago, Rol No. 5.839-2004⁴⁷⁹

Even when during the two previous cases the National Health Institute had no attributions or competences to validate any right derived from patents, and therefore their only duty was to grant sanitary permits within the present case, this theory seemed to bend as the Court started recognising the practical consequence of such permits.

In this case, Centro Juvenil Ages sought to void the sanitary permit granted by the ISP to Laboratorios Grünenthal Chilena Ltda, to commercialise Postinor-2 (with the same abortive effects as Postinol)⁴⁸⁰ also known as the '*after day pill*.'

This court ruling in 2004 contradicts a similar case solved by the Court of Appeals and the Supreme Court in 2001. In this respect, the 20th Civil Court reinforced the Court of Appeals ruling in relation to the "after day pill"⁴⁸¹ by revoking the sanitary permit granted for this pharmaceutical product upon Centro Juvenil Ages's motion. The Court decided to safeguard the rights of the unborn since the pill had the same abortive effects as the aforementioned Postinol. Despite the fact that neither of these cases alleges a breach in the intellectual property legislation, it is important to draw attention to the fact that the sanitary permits began to be addressed as marketing approvals. The distribution of the Levonorgestrel pill, brought to the spotlight the 'real' implications of such a sanitary permit given that it allowed the commercialisation

⁴⁷⁸ Asociación Industrial de Laboratorios Farmacéuticos (ASILFA – Industrial Association of Pharmaceutical Laboratories) is an association dedicated to ensure the maintenance and implementation of conditions that favour the development of the National Pharmaceutical Industry. This Association works with national and foreign laboratories. Original Text in Spanish. Asilfa web, Mission <www.asilfa.cl/mision.asp>

⁴⁷⁹ 20 Juzgado Civil de Santiago, Rol No. 5839-2004, Centro Juvenil Ages Vs. Laboratorios Grünenthal Chilena Ltda./ISP.

⁴⁸⁰ Article 17.10.2 Free Trade Agreement US-Chile

⁴⁸¹ Noriega Alcalá, A., 'Análisis de la Sentencia del Tribunal Constitucional Chileno sobre el Decreto Supremo que Regula la Distribución de la Píldora del Día Después (Levonorgestrel 0.75MG)' *Estudios Constitucionales*, Año 6, No.1, 2008

of a pill that in principle was contrary to the Chilean Constitution, due to its abortive effects.⁴⁸²

On 28 May 2001 the Court of Appeals in Rol No. 850-2001 denied the injunction petitioned by five nongovernmental organisations, among them Centro Juvenil Ages⁴⁸³, against the National Health Institute and Laboratorio Médico Silesia S.A. for the commercialisation of the pill in question. By this time one of the arguments used against the ISP was the fact that by limiting itself to verify if a pharmaceutical product fulfilled the sanitary legislation, at the same time they granted a sanitary permit to commercialise a product with unconstitutional effects. The argument was dismissed and the petitions did not proceed on the basis that no one was actually threatened since they were intending to protect the right of unborn children. Later on that the same year in August the Supreme Court acknowledged the cause and granted in Rol No. 2.186-2001 an injunction against the Lab and voided the Resolution No. 2.141 from the National Health Institute where the *Postinal* was authorised.

Even after the ISP had to withdraw the approval granted for the *Postinal* on 24 August 2001, the same institute granted a sanitary permit for a product named *Postinor-2*, which is manufactured on the basis of Levonorgestrel and causes the same abortive effects.

***30th Civil Court, República de Chile, Rol No. C-6613-2003*⁴⁸⁴**

Within the previous cases it seems like the perception over the marketing approvals or sanitary permits started to shift in Chile, as they are now considered to actually have the power to allow the commercialisation of unwanted products such as the *Postinal*.

This case brings to the spotlight the attributions of the ISP in light of the FTA. In other words, whether or not a linkage existed between the patent office and the ISP. Accordingly, Pfizer obtained a patent for the process to produce *Postinal* and a patent for the product per se; these were to expire in 2003 and 2016 respectively, and consequently a marketing approval was also granted to commercialise the product in 2003. The conflict began in 2003 after Laboratorios Recalcine requested the marketing approval for “known products” before the ISP to commercialise a similar product to the ones already registered by Pfizer.

The Court concluded that by granting a sanitary permit, the validity to commercialise a pharmaceutical product as stated within the Sanitary Code Article number 102⁴⁸⁵ was also granted. Thereafter the Court reached the conclusion that a sanitary permit is an authorisation to commercialise, and that is

⁴⁸² Constitución Política de La República de Chile, Senado de la República de Chile, Available at: <www.senado.cl/prontus_senado/antialone.html?page=http://www.senado.cl/prontus_senado/site/artic/20050516/pags/20050516221649.html>

⁴⁸³ Corte Suprema de Chile, Rol No. 2.186-2001, ONGs' Vs. ISP

⁴⁸⁴ 30^o Juzgado Civil de Santiago, Rol No. C-6613-2003, Porzio Bozzolo Vs. M/Instituto de Salud (2006)

⁴⁸⁵ Sanitary Code (Código Sanitario) Decree N° 725/67 later on modified by Ley N° 20.308

very obvious from the fact that no distribution of pharmaceutical products can be carried out without the mentioned permit.

For the first time in 2006 a Chilean Court actually recognised the existence of a linkage between the ISP and the INAPI. Within the present case, Pfizer Chile S.A. introduced before the court a motion to annul the administrative act through which the ISP accepted and began the process to grant a secondary sanitary permit for Laboratorio Recalcine to commercialise Ziprasidona.⁴⁸⁶

Pfizer is the right holder for the patent for procedures No. 36.533 valid until November 2003 and the patent for products No.41.031 valid until May 2016. Both patents protect the procedure to obtain the Ziprasidone and the product as such and therefore no generics could be commercialised without Pfizer's consent. In 2003 the ISP granted the sanitary permits to the company, so it seems obvious that the Institution had knowledge about the existence of both valid patents and sanitary permits by the time that Laboratorio Recalcine had requested a secondary sanitary permit for the same product and procedure as Pfizer.

One of the issues to be highlighted about this ruling is the fact that the court never denied which were the National Health Institute's attributions and competences, but also did not limit those attributions to a simple requirement fulfilment verification as the previous cases did. In this case the court actually gave a proper interpretation about the linkage and the real duties derived from the sanitary regulation. The question of whether or not the acts executed by this Service are excluded from the applicability of other norms related to patents and property right as such can be raised, enabling them to infringe the rights of others when for example they are analysing similar products.

Data protection and the Chilean Government duties and obligations within the U.S.-CHILEFTA context were also taken into consideration for the ruling that voided Laboratorio Recalcine's sanitary permits request.

***3° Court of Criminal Trial, República de Chile, R.U.C 0510012831-6*⁴⁸⁷**

Following the trend settled with the previous case, this case was one of the most expected cases among the Chilean legal society due to the fact that it was one of the few times when a pharmaceutical company sought criminal enforcement of intellectual property right in Chile. As with the Ziprasidona case, this case seeks to clarify the duties of ISP in regard to the linkage.⁴⁸⁸

Laboratorio Sanofi Aventis sought a court patent infringement in the criminal court for the import, commercialisation and distribution of a pharmaceutical

⁴⁸⁶ I Corte de Apelaciones de Santiago, Rol. 3747-2002, Pfizer Chile S.A. Vs. Laboratorios Recalcine S.A. and the ISP (2002)

⁴⁸⁷ 3° Tribunal de Juicio Oral en lo Penal de Santiago, R.U.C. No. 0510012831-6, Laboratorios Sanofi Aventis Chile Vs. Jaime Kattan (Laboratorios Royal Pharma)

⁴⁸⁸ Read further in "LABORATORIOS NACIONALES VS. INTERNACIONALES / Presunta copia de medicamento reabre la discusión. Propiedad intelectual: farmacéuticas a la espera de fallo que sentará precedente" press Article in El Mercurio Journal from 3 September 2007.

<diario.elmercurio.cl/detalle/index.asp?id={bc1e145d-5f5d-4d4c-a535-88773b61d14c}>accessed 01 September 2009

product name “ISKIMIL” from Laboratorios Royal Pharma, which is a generic version of the original product manufactured by the plaintiff.

The Chilean court condemns the patent infringement for the production of the generic version without the patent owners consent. This was a challenging case that also caused great expectations as Sanofi Aventis’s legal representatives sued Royal Pharma’s legal representatives and general manager. Petitioning to fine Jaime Ramirez Kattan for a sum of 100 monthly tax units (UTM) which if calculated in Chilean pesos is worth around 33 million pesos or 50,000 Euros. The court reached their decision after finding the defendant guilty of a charge according to the Chilean Penal Code Article 15 and Law No.19.039 Article 52.⁴⁸⁹ The reason for suing Royal Pharma’s representative was the fact that he was considered to be carrying out the imports and commercialisation in bad faith,⁴⁹⁰ since Sanofi Aventis is the patent holder for the product PLAVIX⁴⁹¹ which is the original version. Although the court recognised ISP certain liability on the sanitary permit issue it did not go into the matter very deeply, declaring more or less like an issue out of its competences. The trial was full of technicalities regarding the procedure to manufacture the PLAVIX, and several experts within the field were called to the stand to help the court in solving the issue.

4.2.3. Linkage overall assessment

Since Chile ratified the Free Trade Agreement with the United States several challenges regarding intellectual property rights have risen; especially those related to pharmaceutical patents due to the importance to provide fair access to medicines. But the Chilean Administration began working on promoting better access to health care and medicines through Plan AUGE, that will be analysed below, prior the U.S.-Chile FTA. Plan AUGE in brief, is a dynamic system that grants access to opportune and effective health care and according to some studies only one of the pharmaceutical product used is protected by a patent. Therefore, asserting that patents restrain access to medicines in developing countries in the case of Chile could be proven wrong, since Chile is also one of the countries in Latin America with the lowest average price of medicines.

Thus far, the “Linkage” and the marketing approvals seem to challenge for nations, especially those obliged to these kinds of procedures, due to their duties as signatories of “TRIPS Plus Agreements”, but in the case of Chile the challenge

⁴⁸⁹ Law N° 19.039, “Article 52: will be sentenced to pay a fine of twenty five thousand monthly tax units all those: a) who maliciously manufacture, use, offers or introduce into the market a patented invention, or those who import or withhold the patented element with commercial purposes” original text in Spanish, translation by the author

⁴⁹⁰ Código Penal de la República de Chile, “Article 15: The authors of a crime are: 1 those who take part in the execution of an act, whether is through a direct and immediate involvement, or by impeding efforts to prevent or avoid the act” Original text in Spanish, translation by the author. In this case the court found that the general manager was directly responsible for the import, distributions and commercialisation of the product since he was the person authorising such activities

⁴⁹¹ Quinta Sala, I Corte de Apelaciones de Santiago, Rol No.3747-2002, Pfizer Chile S.A. Vs. Laboratorio Recalcine S.A./ Instituto Nacional de Salud (Ziprasidona case). Plavix is the trade name under which Sanofi commercialises Clopidogrel, which is an antiplatelet agent to inhibit blood clots in coronary artery disease, peripheral vascular disease and cerebrovascular disease

or misconceptions about the marketing approval dates from a time even before the agreement was signed as the analysed cases pointed out.⁴⁹²

Moreover, the Chilean sanitary legislation, as reviewed, seems to be using the terms of sanitary permits as synonyms of marketing approvals, and despite the courts contradictions and refusal to acknowledge those permits as marketing approvals, in practice there is no other possible way to assess them differently than being “marketing approvals”.

The issue of the linkage is still to be solved by the Chilean legislators, but nevertheless the feasible truth about the sanitary permits nowadays seems to be more plausible than a few years ago. What still raises questions is why the ISP reformed the legislation on the sanitary permits proceeding and concept after the FTA came in force. And even when the valid regulation refers to sanitary permits, the undeniable fact is that no pharmaceutical product shall be sold without this permit.

4.3. Test Data Protection of Non-Disclosed Information

It is not uncommon to find that data protection restrains access to medicines since the competition will be restricted and generic products will not make it into the market before a period of five years from the registration, in the case of a FTA. Scholars have pointed out that these provisions are designed to require generic producers to render their own clinical trial data instead of relying on the already provided data by the brand name producer.⁴⁹³ Thereafter, market competition will not only be delayed due data protection but also because of the exclusivity granted to the originator product, and because the costs of repeating clinical trials to verify safety and quality to satisfy the regulatory requirements would be very costly and most likely prohibitive enough so as to deter generic competition.⁴⁹⁴

Before discussing further the relevant arguments and the implications of data protection Article 39 TRIPS and Article 17.10.2 U.S.-Chile FTA shall be assessed to understand the main difference between both regulations and the challenges derived from them.

“TRIPS, Article 39.3: Members, when requiring, as a condition of approving the marketing of pharmaceutical ... products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where

⁴⁹² Chile, Instituto de Salud Pública de la República de Chile, Circular No. 14, Santiago 28 de Noviembre de 2001.

⁴⁹³ Sell, S.K., ‘TRIPS-PLUS Free Trade Agreements and Access to Medicines’ (2007) 28 *Liverpool Law Review*, at 45-75.

⁴⁹⁴ Clift, C., ‘Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals’ in Douglass, P., et al. (eds.) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR Oxford: U.K.; PIPRA Davis: U.S.A., Oswaldo Cruz Foundation Rio de Janeiro: Brazil and *bioDevelopments-International* Ithaca: U.S.A.- 2007) at 431-435

necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”⁴⁹⁵

U.S. – Chile FTA, Article 17.10.1: If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical ... product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product ...Each Party shall protect such information against disclosure except where necessary to protect the public.⁴⁹⁶

Article 39.3 TRIPS already foresees Member states’ duty to protect undisclosed test or other data, as the wording denoted within the article, when needed to fulfil regulatory requirements at the moment of a marketing approval registration. The duty to protect this kind of data against unfair commercial use or competition is assessed by the TRIPS in the first place and then by the FTA. The U.S. – Chile FTA among other clauses incorporates the need to protect this data for a period of 5 years, but it must also be highlighted that as denoted from the article itself the wording and duties for the party are much more defined than in the TRIPS Agreement.

Both articles take into consideration the protection of data for those products that utilise a new chemical entity, and the exception for protecting such data are those cases when it is necessary to protect the public. A question arises though about the mention of ‘protection of the public’: If this brief and unelaborated mention enough to address public health emergencies, to enact a compulsory licence even if breaching the data protection clause or to allow parallel imports within the country to satisfy the local market needs?⁴⁹⁷

Some scholars point out that the data exclusivity right is a much stronger right than the intellectual property right because this regime does not possess flexibilities that allow governments to adapt their legislation accordingly with their needs.⁴⁹⁸ Adding to the discussion, data exclusivity may act as a barrier for compulsory licences since this could prevent a compulsory licence on an equivalent product to the one patented or with data exclusivity. A part of the doctrine disputes the differences between data protection and data exclusivity, pointing out the first one as the protection of trade secrets and the second one as the right granted to the originator of a product which uses a new chemical entity that is not necessarily protected by a patent.

The problem posed by data protection, either by TRIPS or the FTA, has also to do with the implementation of such a regulation. In the Chilean case, it is known

⁴⁹⁵ Article 39 (3) from TRIPS Agreement

⁴⁹⁶ Gobierno de la República de Chile, Decreto N° 312 del 01 de Diciembre de 2003, Publicado en Diario Oficial el 31 de Diciembre de 2003

<www.bcn.cl/lc/tinterna/tratados_pdf/tratado_vallyo72.pdf> English version

<www.ustr.gov/sites/default/files/uploads/agreements/fta/chile/asset_upload_file941_4019.pdf> accessed 14 September 2013

⁴⁹⁷ Parallel imports under the TRIPS Agreement are allowed as long as they are to satisfy local market needs, as highlighted by Article 31 (f).

⁴⁹⁸ Clift, C., ‘Data Protection and Data Exclusivity’ at 434.

that PhRMA has been lobbying to enforce a data protection regime that portrays an efficient system against unfair competition.

Data exclusivity seems to be an issue in Chile:: during the same Special Senate Session where an analysis about the pharmaceutical industry in Chile was carried out in 2009, the illegality of Article 8 from the Decreto Supremo N° 153 A circulated during 2007. The aforementioned Decree is nowhere to be found and on the Library of Congress database Decree 153/2005 remains in force.

4.3.1. Bolar Exemption

The Bolar exemption is dealt with in Article 17.9.4 of the FTAA. This provision, as some authors suggest, looks forward by preparing the entrance of generic pharmaceuticals as soon as the patent expires.

This issue must be linked to the fact that, allegedly, in Chile the manufacture of copied medicines from patented pharmaceuticals represents a 45% share of sales⁴⁹⁹ in the market. The Chilean President at the moment of signing the treaty ratified the administration's position on this issue, highlighting that within the context of the treaty there are mechanisms available to allow third parties the use of protected data with the purpose to further commercialise those products once the patent has expired.⁵⁰⁰ Thereafter, even when the President settled the government's position on the matter, the fact that the internal legislation allows the use by third parties of protected data before the patent has expired might be seen by their trading party as an alarming situation leading to a breach in the treaty.

Within the context of the agreement there are two articles dealing with the extra time given to patent owners due to unreasonable delays when granting a patent. These articles are 17.9.6 and 17.10.2, whereas the first one establishes the general grounds when making available the option of the term extension, the second only regards pharmaceutical products.

4.4. Chilean Health Care System

The right to health care in Chile is given by Article 19 part 9° where the State gives citizens the opportunity to access health care through private or public means.⁵⁰¹

⁴⁹⁹ Hartwig, G., Chilean Pharmaceutical & Medical Devices Market Overview 2009 (OSEC + Business Network Switzerland: 2009) 1-128<www.s-ge.com/sites/default/files/bbf_chile_pharmaceutical_market_2009.pdf> accessed 14 September 2013

⁵⁰⁰ Cousiño, J.M., 'Tratados de Libre Comercio.' Also, 'Bachelet dijo que TLC con Estados Unidos no le quitó soberanía a Chile' El País Digital, 6 November 2006 <historico.elpais.com.uy/06/11/06/pnacio_246032.asp>accessed 10 March 2013.

See Carey, G., 'La Protección de Exclusividad de Datos' in La Propiedad Intelectual en Chile y Tratado de Libre Comercio EE.UU, Serie de Estudios Técnicos AmCham, Documento Nro. 2<www.amchamchile.cl/sites/default/files/SET%20documento%202%20actualizado.pdf> accessed 10 March 2013

⁵⁰¹ Constitution of Chile, Article 19 part 9°: "The right to protection of health. The State protects the free and egalitarian access to actions for the promotion, protection and recovery of the health

This part of the chapter focuses on public health policy in Chile, assessing the main health programmes and provisions related to both access to medicines and health services in Chile.

The current health care system is constituted by compulsory social health care insurance that is granted by both public and/or private health care providers in accord with the Chilean public health legislation. The Plan de Salud con Garantías Explicitas – GES (Health Plan with Explicit Benefits) is the one defining the guaranties that are to be granted within the social insurance scheme. GES is the reformed version from Plan AUGE- Acceso Universal de Garantía Explicitas (Universal Access with Explicit Benefits Plan), that was nothing more than a universal social health care system, as will be explained below.⁵⁰²

History reveals the different stages the Chilean health care system has undergone that were required for it to evolve to the point where it is nowadays. Furthermore, to understand the relation within the pharmaceutical patents and the access to medicines in Chile, an analysis will be carried out to understand the public health care system.

4.4.1. Chilean Health Care System before Plan AUGE

Before President Lagos implemented the Plan AUGE in 2004, the Chilean health care system had a different structure. The previous system was based on a separation between blue and white-collar workers. At the end of 1952 the Servicio Nacional de Salud - SNSS (National Health care Service) was created in Chile through the Ministerio de Salud (Ministry of Health). This new institution would follow the philosophy, objectives and organisation used by Great Britain when it created the British National Health Service to provide medical attention four years earlier.⁵⁰³ At a first glance the health care system in Chile separated blue-collar workers and indigents received medical attention through the National Health Service while the white-collar workers and civil servants received medical attention through the Employees Medical Services, also known as SEMERNA. While the State bared the entire weight of the health care system during the

and rehabilitation of the individual. The coordination and control of activities related to health shall likewise rest with the State. It is the prime duty of the State to guarantee health assistance, whether undertaken by public or private institutions, in accordance with the form and conditions set forth in the law, which may establish compulsory health quotations. Each person shall have the right to choose, the health system he wishes to join, either State or private- controlled.” Original text in Spanish, translation in English <confinder.richmond.edu/admin/docs/Chile.pdf> accessed 10 March 2013

⁵⁰² Bastías, G.. and Valdivia, G., ‘Reforma de Salud en Chile; El Plan AUGE ó Régimen de Garantías Explicitas en Salud (GES). Su Origen y Evolución’ (2007) 32 *Boletín Escuela de Medicina U.C. Pontificia Universidad Católica de Chile* 2,51-58

⁵⁰³ Cerededa T., L.. and Hoffmeister, L., ‘La Reforma de Salud en Chile: Cambios Constitucionales, Logros y Dificultades en su Implementación’ in The Center for Migration and Development, Working Paper Series #08-05e, (Princeton University, December 2008) <www.princeton.edu/cmd/working-papers/idlaco8/wpo805e.pdf> accessed 10 March 2013

Allende period, the Pinochet regime adopted a more market-oriented strategy where the health care would be framed under the idea of the subsidiary state.⁵⁰⁴

The need to expand the health care system to every citizen during the 1960s led Presidents Eduardo Frei and Salvador Allende to carry out massive expansion of the health care system to forgotten sectors such as the rural and the self-employed urban workers. By late 1960 the health care system covered 71.9% of the population, and by the end of 1970 the system granted health care protection to 80% of the population.⁵⁰⁵

4.4.2. Health Care Reform: 1973-1989

The Pinochet regime (1973-1989) was characterised among many other things -as highlighted at the beginning of the chapter- for introducing the idea of a subsidiary state, which aimed to amend the State provisions of social services and regulatory activities, transferring those to individuals and private health care providers.⁵⁰⁶ These private health care providers were to be regrouped in 1981 under the Instituto de Salud Previsional – ISAPRES⁵⁰⁷ (Private Health Insurance Funds) and offered medical insurances and workman’s compensation packages. Usually these entities required a 7% payroll contribution plus the 2 or 3% of additional premium, which was agreed between the ISAPRE and the beneficiary depending on the size of the package offered by the ISAPRES.⁵⁰⁸

As far as public health care policies go, these have never been separated from the political situation governing a country. It is a well-known fact that the Pinochet regime in Chile was authoritarian. During the Pinochet regime and the regime’s market oriented mechanisms, the privatisation era began within the health care sector, as the regime believed that the country should have less involvement in that area. None the less, the past leaders of Chile all have seen the necessity in developing a strong health system and to a certain extent during the past 50 years health became a public matter and therefore both dictatorial and democratic governments have sought health improvements for Chilean citizens.⁵⁰⁹

Moreover, the privatisation of the Chilean health care system in 1981 meant that the solidarity concept used when defining the system changed from using three financing sources (state, employees and workers) to a private and mixed model. In this new model, those who would prefer the private health care system would

⁵⁰⁴ Borzutzky Yozmot, S., ‘Health in Chile: is the Government Doing Everything it can to Achieve Social Justice?’ (September 2008) 27 *Medicine and Law*, at 645-659

⁵⁰⁵ Borzutzky, S., ‘Social Security and Health Policies in Latin America: The Changing role of the State and the Private Sector’(1993)28 *Latin American Research Review* 2, at 246-256

⁵⁰⁶ Borzutzky, S., ‘Health in Chile’ at 646

⁵⁰⁷ ISAPRESS are private health services providers created in 1981 with the Healthcare reform. This Institution receives the mandatory health fee paid by workers from those who choose to use the private healthcare services. Information available in Spanish at: <www.ISAPRESS.cl>

⁵⁰⁸ Cartin, B., ‘The Effectiveness of the Reform’ in Cruz-Saco, M.A., and Mesa-Lago, C., (Eds.) *Do Options Exist? The Reform of Pensions and Healthcare systems in Latin America*, (Pittsbourg University Press, 1999) at 210 quoted by Silvia Borzutzky in “Health in Chile: is the Government Doing Everything it Can to Achieve Social Justice?” in 27 *Med. & L.* 645, September 2008

⁵⁰⁹ Román A. O., et. Al. ‘Una mirada crítica en torno al plan AUGE. Algunos aspectos generales y valóricos’ (2008) 136 *Revista Médica de Chile*, 1599- 1603

pay the mandatory health fee directly to ISAPREs, and those who would not earn that much would make use of the public health care system. This public health care system was regrouped under the Fondo Nacional de Salud – National Health Fund (FONASA). Apparently, by then there was a mix between who were the FONASA beneficiaries as there also was a small differentiation among workers and employees. This last fact led to a legal reform where workers and employees would benefit from the use of the public health care system as long as they would contribute to the system according to their salary level;; the new law allowing both workers and employees to enjoy the public system was Ley N° 18.469.⁵¹⁰

The health care reform did not only restructure the way the health care system was to work in Chile, in the sense of service providers and who would have access to which kind of health care. The reform also implied changes within the administrative and efficiency functions. The administrative part had to do with the decentralisation of the 26 autonomous services provided by the Sistema Nacional de Servicios de Salud (SNSS) created in 1952. The control and legislative responsibility would remain as part of the Ministry of Health's duties, the hospitals' administration would now be the responsibility of those Servicios de Salud and the primary health care establishments would go under the municipalities' administrations.⁵¹¹

Regarding the impact on efficiency due to the administrative structure explained above, it is important to highlight that the budgeting structure was also handled in a different manner. Previous to the decentralisation of the health care system, the budget was assigned according to the historic or past year's expenditure records. The new system was deemed to be more direct, canalising hospitals' budgets according to invoices for used services, and health care provided at a municipality level was calculated on the basis of the invoices for used services within the municipal level to pay for doctors' offices.⁵¹²

4.4.3. Health Care Reform: 1990-2002 (two democratic governments)

While the previous health care reform focused on the private health care sector, the new health care reform proposed by President Allan Aylwin, during a period also known as Primer Gobierno de Concertación (The First Consultation Government), focused on rescuing the public health care system, which at the time was considered to be neglected by the previous government. Among the problems found within the system, was the lack of financial sources to cover costs of treatment and to provide the services as such. Therefore, during this period a tax reform was also necessary to increase the public health care budget. After raising general taxes the health care budget increased 33% between 1991-1992, thus allowing salaries, operational recourses and pharmaceutical expenditures to be improved.⁵¹³

⁵¹⁰ Oyarzo, C., 'La Mezcla Público – Privada: una Reforma Pendiente en el Sector Salud' (Invierno 1994) *Estudios Económicos* 55,143 – 170

⁵¹¹ Cerededa, L., et al. 'La Reforma de Salud en Chile' at 3

⁵¹² Idem at 11

⁵¹³ Oyarzo, C., 'La Mezcla Público – Privada' at 12

Accordingly, the gross domestic product increased from 0, 7% to 1, 3% during the year 1989 and between 1996 and 2003 it was up 6,1%. This was perceived as a beneficial fact, as in those years the state's health expenditure increased by 140%, and this was also financed by the tax reform.⁵¹⁴

Even though the first democratic period emphasised rescuing the public health care sector, during the second period in 1994 the ISAPREs continued subscribing more affiliates due to dissatisfaction with the performance of the public sector.⁵¹⁵ Initially, those who could afford private health care insurance chose to pay the 'ISAPRE's mandatory contribution and its co-payments, but those who were not financially capable had to receive medical attention from the public sector. The new democratic era denoted efforts and interest in balancing the health care system and therefore worked towards providing better access to primary health care within the public system. Moreover, in 1994 Chile introduced an innovative Family Health Plan (Plan de Salud Familiar), which was intended to provide a basic package of health interventions in accord with the demographic and epidemiological variations.

During the previous political regime, the health care sector was decentralised and provided a different structure, and therefore a new funding and payment structure needed to be redesigned. Even when the primary health care was the focus of this new period, the government implemented a "diagnosis related payment" (PAD) aiming to define a set of standard interventions associated with a determined diagnosis and the cost would be estimated as an average, making the services less expensive for secondary and tertiary health care. Another important step within the period was to eliminate the mixed subsidiaries for the health care sector that had existed in the past.⁵¹⁶

Both democratic terms aimed at restructuring the health care sector, but the second term worked towards regaining the trust of health care beneficiaries within the public sector. Hence, an important legal reform in 1999 was needed to redefine FONASA's mission by transforming it into a public health insurer, providing that this institution would be responsible for raising its own funds by collecting fiscal contributions, co-payments and national insurance contributions from its beneficiaries to pay for health care service providers.⁵¹⁷

Chilean history denotes that there were three important health care reforms leading to the new Plan AUGE - GES health care system. Their main characteristics were: (a) the 1952 health care reform nationalised the Chilean health care system, defining financial matters and designating the service providers; (b) the Neoliberal or Pinochet reform in 1981 was based on market freedom and health care privatisation; and c) the 1990-2003 period was characterised by rescuing the public sector and turning it into a public health care insurance by granting access to health care to every Chilean citizen.

⁵¹⁴ Cerededa, L., et al. 'La Reforma de Salud en Chile' at 14

⁵¹⁵ Barrientos, A., 'Health Policy in Chile: The Return of the Public Sector?' (2012) 21 *Bulletin of Latin American Research* 3, at 442-459

⁵¹⁶ Barrientos, A., 'Health Policy in Chile' at 443

⁵¹⁷ Correa, C., 'Un mal negocio de Chile con Estados Unidos', *Le mond Diplomatic*

4.4.4. Plan AUGE - GES 2002-2008

The right to health and the principles of equal access to health, efficiency and social participation inspired the new health care reform in 2002. These principles were also taken into consideration by past rules, but the implementation of the new health care system that was being drawn required the development of an innovative legal base.

As mentioned above, defining issues such as funding, structure, regulatory entities, rights and duties and the health care system itself were of great importance to the success of implementing this new reform. Moreover, five relevant legal projects within the reform have been identified, namely, the laws defining patient's rights and duties, funding sources and methods, the health and management authority, the ISAPRE's law and the regime for health guaranties, also known as GES.

Each of these projects had a specific purpose: (a) Patient rights and duties: this law defined and regulated legal remedies and measures taken against health providers, either public or private; (b) Funding sources: this law estimated to increase value added taxes (VAT) by 1% to support the health care system and the creation of new health care tax destined to finance the Régimen con Garantías Explicitas en Salud – GES (Regime with explicit guaranties in Heal) for all of those FONASA beneficiaries; (c) Health management authority: intended to strengthen the health care authority by delimitating functions and duties. Leaving regulatory and fiscal matters to the Ministry of Health, and the management and administrative matters were left for the Red Asistencial (assistance network; (d) ISAPRE's Law: foresaw the creation of a surveillance and control entity for those health care service providers, taking care of health care plans prices, service catalogues and information; and (e) GES: establishes a mandatory health care plan for FONASA and ISAPRES.⁵¹⁸

After introducing the main legal projects supporting the health care reforms, Plan AUGE requires further explanation and why it is considered to be one of the most innovative plans implemented in Chile and perhaps in Latin America regarding health care. AUGE stands for Acceso Universal con Garantías Explicitas (Universal Access with Explicit Guaranties) and the Explicit Guaranties in Health are known as GES. Within the lines above, GES was referred to the regime for health guaranties as well as for the explicit guaranties in health, which given by Law No. 19.966, Article 1 are the same. This Law defines GES as the legal instrument designed to regulate the Health care services regime, which at the same time is constituted by a sum of explicit guaranties destined to foresee access, quality, financial protection and opportunity.⁵¹⁹

Accordingly, in 2005 Plan AUGE started providing treatment for 25 basic diseases, which included the different diagnoses and a strict use of protocols for practitioners when treating those diseases⁵²⁰. In all, 16 diseases were added to the

⁵¹⁸ Bastías, G., and Valdivia, G., 'Reforma de Salud en Chile; El Plan AUGE' at 52

⁵¹⁹ Ley No. 19.966, República de Chile, Ministerio de Salud, Establece un Régimen de Garantías en Salud.

⁵²⁰ Decreto N°170. CHILE. Aprueba Garantías Explicitas en Salud del Régimen General de Garantías de Salud. Ministerio de Salud, Publicado el 30 de Enero de 2006
<www.leychile.cl/Navegar?idNorma=235073>accessed 10 March 2013

disease list in 2006, another 16 in 2007⁵²¹ and seven more were added as a pilot plan during 2008,⁵²² meaning there were 64 diseases covered by GES. The goal of Chile is to provide proper care for 80 diseases that afflict the Chilean population. Integral maternity care, including pre and postnatal subsidy, hypertension, diabetes, cancer and HIV/AIDS are among the conditions treated within the Plan AUGE.

The Chilean Government committed to providing its nationals with four explicit guaranties when protecting the 64 current treated diseases in Chile since the early democracy days. These explicit guaranties are defined as: (a) Explicit guarantee of access: is the obligation given by law to FONASA and ISAPRES to ensure the benefits are granted to all the beneficiaries; (b) Explicit guarantee of quality: understood as the duty to provide guaranteed health care by a registered or accredited provider; (c) Explicit guarantee of opportunity: defined as the need to comply with a deadline to provide care for the health benefits granted by law; and (d) Explicit guarantee of financial protection: regarding the members or beneficiaries' duty to fulfil their contribution, payment or co-payment due health care fees and or group of benefits ensured.⁵²³

Plan AUGE –GES, covers at this point 56 diseases and seven more are being implemented in a pilot plan. Patients and beneficiaries will pay a deductible of 20% from the total attention cost and patients with no means of support will have access free of charge. If patients would like to receive full coverage for the treatment of those highly costly diseases then they can subscribe to a complementary insurance from either ISAPRE or FONASA. The private health care insurance requires further co-payments whilst the public one does not.

It should be mentioned that Ley N° 18.469⁵²⁴ classified Chilean beneficiaries within the Article 160, ante 29, in four groups according to their income level.⁵²⁵ The main idea with this structure was to define fair deductibles and co-

⁵²¹ Decreto N° 44, Publicado en Diario Oficial de 31.01.2007, Ministerio de Salud, Garantía Explícitas en Salud del Régimen de Garantías en Salud

⁵²² Dra. María soledad Barría, AUGE 2005 – 2008 Implementación de garantías explícitas en salud, Ministry of Health, 14 de Agosto de 2008

⁵²³ Biblioteca Nacional del Congreso de Chile, “Guía Legal sobre Plan GES” in Ley Fácil <www.bcn.cl/guias/plan-ges-ex-auge> accessed 14 September 2013

⁵²⁴ Decreto con Fuerza de Ley N°1. CHILE. Fija el texto refundido del Decreto Ley N° 2.763, de 1979, de la Ley N° 18.933 y Ley N° 18.469. Ministerio de Salud, publicado en fecha 23 de Septiembre de 2005 <www.leychile.cl/Navegar?idNorma=249177> accessed 10 March 2013 (hereinafter Decreto N° 1)

⁵²⁵ Article 160 from Decreto N° 1: “for the purpose of the established within the precedent article, those affected by this legislative piece will be classified according with their income level in the following groups; Group A: homeless, people with scattered resources, assistance pensioners beneficiaries referred within the Law Decree N° 869 and those family subsidies receivers established within the Law N° 18.020; Group B: subscribers with a monthly income not exceeding the minimum wage foreseen for those workers not younger than 18 years old and not older than 65 years old; c) Group C: subscribers whom their monthly income is above the minimum salary but that does not exceed a 1, 46 times from the minimum wage, unless from the main beneficiary has three or two dependants case in which the subscriber will be classified under the Group B; Group D: subscribers who's monthly income is higher than 1, 46 times above the minimum wage ... and who's dependants do not exceed from two. In case of having more than two dependants the beneficiary will be classified within the Group C.” The minimum wage at the moment in Chile is \$165.000,00

payments to health care providers due health care attention. The groups in question are A, B, C and D. Whereas group A and B receive total free health care attention, groups C and D generally will have to cover 20% of the total price for the medical care provided to them. The exception to this rule is when it comes to dental health care attention, in which case Group B will pay 30% of the total value, Group C 50% and Group D 80%.⁵²⁶

The basic and mandatory premium for health care is 7%, thus this entitles citizens to either make use of the system through the Modalidad de Atención Institucional –MAI (Institutional Attention Pattern) or the Modalidad de Libre Elección –MLE (Free Choosing Pattern). These two patterns are differentiated by the fact that the MLE is only accessible to those within groups B, C and D as previously mentioned; and because if someone needs medical attention under the MAI he or she will receive medical attention only during the available times designated by the hospital, whereas the MLE allows patients to be treated by a chosen attendant at the time that suits the patient instead of having to wait until there is an available time.⁵²⁷ Of course, in case of medical emergency the Chileans are treated immediately.

Accordingly, after the primary health care attention there are complementary benefits within the system to ensure higher coverage and less money expenditure on the behalf of the Chileans. These plans existed before Plan AUGE's implementation, namely the FONASA Catastrophic insurance (Seguro Catastrófico de FONASA), the Elderly Programme (Programa Adulto Mayor), and the Opportunity Attention Programme (Programa Oportunidad en la atención). These programmes should fasten up response times and coverage for the treatment of certain diseases.

Both FONASA and ISAPRES offer extra coverage for what are called catastrophic diseases, which are generally considered as those forcing individuals to pay an equivalent to 40% or more from the family income to overcome a health care treatment thereafter obstructing the treatment finalisation due to medical and pharmaceuticals costs.⁵²⁸ The difference between the insurance offered by ISAPRES and FONASA is that the ISAPRES one is not only called Cobertura Adicional para Enfermedades Castastróficas – CAEC (Additional Coverage for Catastrophic Diseases), but also requires extra payment on the beneficiary's behalf whilst the FONASA insurance seems to be free of charge; and the groups allowed to take the extra coverage are B, C and D as they also initially chose to be served under the MLE pattern.

One important remark about the MLE is that it allows affiliates to choose from those clinics affiliated to FONASA or those with collaboration agreements with FONASA, otherwise the system would work as normal private health care insurance.

(Chilean pesos) equivalent to \$305,00 (American Dollars). Boletín N° 6568-05, Departamento de Prensa, Valparaíso, Senado de la República de Chile, 17.09.2009

⁵²⁶ Plan de Salud, FONASA available at: <www.fonasa.cl>

⁵²⁷ Ibid.

⁵²⁸ FONASA, *La Protección social en Salud en Chile* (FONASA publicaciones, Libro N°2 -2007) at 69

<www.fonasa.cl/prontus_fonasa/site/artic/20070413/asocfile/libro_proteccion_social_en_salud_en_chile.pdf> accessed 14 September 2013

4.4.5. Importance and Social Impact

Plan AUGE - GES was a great improvement for Chile's health care system, but it also seemed to have some critique on behalf of opposing governmental parties as in practice financing the system did not seem possible and therefore new measurements were also to be considered for the success of the programme. The new financial means were to be guaranteed by new taxes on alcohol, tobacco, gasoline as well as raising the VAT and the creation of a solidarity fund to finance the health care system. This solidarity fund was to take a 0.6% off from the 7% health tax paid to ISAPREs to finance the new maternity fund, which was to pay pre and post natal subsidies.⁵²⁹

Nowadays, and according with a FONASA report, the health care sector in Chile is financed primarily by fiscal contributions equivalent to 32,1% in 2004, social security compulsory contributions equivalent to 37,5% and the so-called fair pocket expenditure⁵³⁰ equivalent to 30,4%.⁵³¹

Besides finding out which are the funding sources for Plan AUGE – GES, what matters is to demonstrate that countries such as Chile have been able to achieve an extensive health care protection plan that includes detection and treatment for cancer, asthma and HIV among many other diseases at a very low cost or at no cost whatsoever for patients. The Decreto N° 44 of 2007 in its Article 2° defines what stands for benefits among some other relevant definitions: benefits stands for health actions, technology or medicine units, exams, procedures and most importantly entails the distribution of medicines to beneficiaries as long as they belong to those 56 or 62 pathologies covered by GES.⁵³²

Reducing the pocket expenditure of medicines is another important achievement of the health care reform in Chile. This kind of expenditure is due to purchases of pharmaceuticals by individuals at their own expense when the AGES-GES does not cover those medicines.

The Chilean government with the Plan AUGE looked forward to granting adequate access to health care independently of its citizens' payment

⁵²⁹ Borzutzky Yozmot, S., 'Health in Chile' at 645

⁵³⁰ Generally, the pocket expenditure is regarded as fair when certain social protection conditions are met, such as: a) this expenditure should not exceed 40% of a family monthly income as in that case the expenditure due medicine costs or disease treatment will be qualified as a catastrophic expenditure; b) healthcare costs should not increase or place families in a situation of poverty; c) healthcare distributions of costs should not augment inequality; and d) the social differentiation among the beneficiaries' groups do not become even *more* evident due to income insufficiencies when treating a disease. FONASA 2007

⁵³¹ *Ibid* FONASA

⁵³² Artículo 2°, Decreto N° 44 de 2007, Garantías Explícitas en Salud del Régimen General de Garantías en Salud, publicado en el Diario Oficial de 31.01.07, by el Ministerio de Salud de la República de Chile – Departamento de Asesoría Jurídica. Spanish Official language. "Article 2° for the present chapter the following definitions stands for: ...g) Benefits: health actions, technology or medicine units, such as doctors consultations, medical tests and procedures, medicines; pharmaceutical and laboratory appliances surgical material, supplies and other elements or appliances needed to provide the patient with a health diagnosis and treatment..."

capabilities.⁵³³ Moreover, due to the financial protection guarantee foreseen in GES a Chilean can rely on the fact that he or she will not pay more than the 20% deductible due to medical services or medicines; this is with the exception of those citizens who agreed upon an extra coverage with an ISAPRE or those FONASA citizens with coverage provided by any of the plans offered by that institution. The health care plans are measured or estimated in pesos or UF – unidad de fomento (unit of account), and the unit of account is used to express prices and is adjusted according to inflation.⁵³⁴ According with the data provided by the Chilean Central Bank, the unit of account is equivalent to \$20, 974.19 Chilean pesos and there is a minimum wage of \$165,000 Chilean pesos as denoted in footnote 27.

Within the financial guarantee, not only the deductibles but also the fact that a worker is protected 100% when they need to take days off from employment due to illness could also be taken into consideration. Meaning, that a worker will be subsidised or continue to be compensated as if he will be attending his job regularly. The Chilean health care system or its providers will write a *Licencia Medica Curativa* – LMN (sick leave) to the ill worker, and this will also be registered in a National Formulary of LMC. This LMN is used as well to prevent frauds in the health care system in the sense of workers taking leave of absence with no real cause and been compensated by their job; the permit also allows authorities to keep the relevant data, such as medicines subscribed, days of sick leave and treatment to follow.⁵³⁵

Another point against AUGE – GES is that since both the private and public health care system are bound to cover the diseases or health care problems, the state might be assuming higher costs due to aging beneficiaries changing from ISAPRES to FONASA when they are not able to pay for the higher premiums and co-payments imposed by the “private insurer” to cover catastrophic illnesses⁵³⁶. FONASA seems to be registering 40% of poor or unable to contribute beneficiaries, which eventually may compromise health care quality and efficiency.

Despite the observations on GES and the Chilean health care system, up to 2010 the perception over the reform seems to be positive. According to WHS statistics, by 2006 the Chilean Government was spending 5,2% of its GDP on health care, about 360\$ on every citizen and even though the average health expenditure is 8,7%, Chile managed to increase life expectancy to 77 years old and reduce infant mortality significantly after AUGE GES was implemented.⁵³⁷ The data offered by

⁵³³ Arrau C., F., ‘Conceptualización del Plan de Acceso Universal con Garantías Explícitas (AUGE), eje de la Actual Reforma a la Salud’ in *Serie de Estudios de Anticipación/CEA/BCN*, Año I N 1, Abril 2002

⁵³⁴ Shiller, R., ‘Indexed Units of Account: theory and Assessment of Historical Experience’ in *Documento de Trabajo del Banco Central de Chile*, N° 28, April 1998

⁵³⁵ Mesa, F., et al, ‘Fraudes a los sistemas de Salud en Chile: un modelo para su detección’ (2009)1 *Revista Panamericana de Salud Pública* 25, at 56 – 61

⁵³⁶ Bes, M., ‘Public tensions, private woes in Chile’ (2008) 86 *Bulletin of the World Health Organization* 11, < www.who.int/bulletin/volumes/86/11/en/index.html > accessed 14 September 2013

⁵³⁷ Organización Mundial de la Salud, *Estadísticas Mundiales 2009*, in *Catálogo de la Biblioteca de la OMS*. <www.who.int/whosis/whostat/ES_WHS09_Full.pdf> accessed 14 September 2013

the report highlights that Chile's GDP expenditure in health care is around 15 times lower than the health care expenditure of the United States of America.

Chilean society counts with a dual system that aims to complement both the private and public health care systems through an elaborate insurance system. Some would argue that the State is forcing ISAPRES to compete against FONASA so as to offer better incentives and therefore gain more affiliates. Apparently the public health care insurance system seems by far more appealing to those with a higher risk and those with less resources; and the private due to better quality and efficiency turns out to be more appealing for those with better income. A consumer behaviour study highlighted how some would make use of both the private and the public health care system: people would purchase the ambulatory insurance from the ISAPRE while at the same time signing in for the catastrophic insurance offered by FONASA, which is free of charge.⁵³⁸

Having mentioned the health care system structure, it must also be mentioned that the ISAPRES has its own duality, as it can either be an open or a closed system. This means that the open ISAPRES receives the mandatory contribution of every worker who chooses to do so, but only eight⁵³⁹ ISAPRES providers are registered to receive the mandatory contribution and provide the "private" health care insurance. Whereas, the closed ISAPRES will only provide health care attention to employees of companies affiliated to that specific ISAPRE. These employees generally have better incomes and they can afford the regular private health care insurance system.

The ISAPRE is understood as the bodies relieving the State from those functions that can be carried out by private parties and that at the same time operate on a competition system within the private health care insurance sector.⁵⁴⁰ The fact that the ISAPRE needs to offer competitive health care plans according to some studies has become a very challenging task, as competing against the public health care system where a beneficiary or affiliate is able to receive total coverage for those catastrophic diseases free of charge (FONASA) turns out to be by far more attractive than having to pay an extra fee due health care plans. Accordingly, the product offered by ISAPRE is structured in two parts: the first one covers the GES guarantees, and the second is the Plan de Salud Complementario (Complementary Health care Plan) of which the benefits to the user cannot be lesser than those provided by FONASA within the MLE pattern highlighted above and the price of which shall be determined by depending on the beneficiary's age, gender and quotation group.⁵⁴¹

⁵³⁸ Sapelli, C., et al., 'The Mandatory Insurance System in Chile: Explaining the Choice between Public and Private Insurance' (2001) 1 *International Journal of Healthcare Finance and Economics* 2, at 97- 110

⁵³⁹ An interesting fact is that isapreschile.cl registers only eight accredited ISAPRES and the Chilean Superintendence registers 14 ISAPRES providers. By 2009, further agreements with healthcare providers or insurers were reached

⁵⁴⁰ Superintendencia de ISAPRE, ¿Cuáles son los beneficios del Sistema Isapre?, in Guía del Usuario, 2001. <alegislativo.bcn.cl/alegislativo/pdf/cat/docs/2981-11/200.pdf> accessed 14 September 2013

⁵⁴¹ Sánchez, M., et al., *Producto y Precios en el Sistema ISAPRE* (Septiembre 2001) Documento de Trabajo – Departamento de Estudios y Desarrollo, Superintendencia de Salud

If the statistics from the World Health Report in 2000 on Health Systems and WHO statistics on performances, which were provided previously, are compared it is possible to find how the life expectancy has changed in Chile from 1997 to 2006. In 1997 the life expectancy was 66 years and by 2006 it had increased to 77 years. The GDP expenditure on health decreased from 6.1% in 1997 to 5.2% in 2006.⁵⁴² This WHO report from 2000 put Chile in 33rd place worldwide when assessing the health system attainment and performance; interestingly enough, even though at that time AUGE-GES was not implemented, Chile managed to move up the rankings for improving its health care.

4.5. Chilean Health Care and Pharmaceuticals

One of the social positive remarks as mentioned above is the fact that Plan AUGE – GES provides free medication for the treatment of those diseases covered within the plan, as long as the protocols foresee it. The Chilean effort in improving access to medicines becomes visible when dealing with the HIV/AIDS pandemic. In September 2006, the *Mercurio* Journal highlighted how the governmental policy and efforts in treating such a disease were seen by the international community, which qualified Chile as an example to follow jointly with Argentina, Brazil, Costa Rica and Mexico among the countries providing by 2006, 100% therapy coverage for HIV treatment.⁵⁴³

As highlighted above, each disease has a protocol to follow when preventing-treating-following a disease covered within Plan AUGE. These extensive and detailed protocols are also been objected to by part of the Chilean society, as it is believed that the health care sector will be object of legal intervention and schematisation on behalf of the health care providers and beneficiaries. When reading the protocol and clinic guide for the HIV/AIDS treatment in Chile,⁵⁴⁴ it is possible to find the antiretroviral used for this disease and the majority of them are generic versions, possibly only one of them is a patented product. HIV/AIDS is one of the critical topics dealt with in the context of health care within developing, least developed and developed nations since providing access to affordable medication has been highlighted to be crucial in the fight against the illness. India, Brazil, Chile and many African countries are among the acknowledged nations which due to innovation not only provide suitable treatment, but which also ensure affordable treatment for citizens. In this respect, Chilean public health care policies seem to have been reformed with the aim of striking a balance between their international duties and social needs.

Within the context of the present chapter it has been mentioned several times that AUGE – GES covers 56 diseases and that 7 were being implemented in a

Quotation group shall be understood as the groups used by the Chilean healthcare system to classify its users or beneficiaries. e.g Group A,B,C or D as explained above.

⁵⁴² *The World Health Report 2000 – Health systems: Improving Performance*, World Health Organization, Geneva (2000) 1-206 <www.who.int/whr/2000/en/whr00_en.pdf> accessed 10 September 2013

⁵⁴³ Editorial, E. M. Medicamentos y AUGE. *El Mercurio*. (1st-September, 2006).

⁵⁴⁴ See further, Guía Clínica – Síndrome de Inmunodeficiencia Adquirida VIH/SIDA, in Series de Guías Clínicas (MINSAL – 2009) at 74 <www.redsalud.gov.cl/portal/url/item/7220fdc4340c44a9e04001011f0113b9.pdf> accessed 14 September 2013

pilot programme, but what are these diseases and what do the protocols and clinical guides cover. The table in (Annex 1) highlights the type of attention provided and if medicines are given to the beneficiaries to treat the disease.

In 2008 eight more diseases were being treated in a pilot form, and then in 2009 eight additional diseases were added. The curious thing is that by 2008 the Ministry of Health on its web page only showed the clinic guides for 7 diseases, and with respect to the 2009 one, only two guides are available. Although, in both cases, the site states that these are the 8 guides for the Pilot AUGÉ – GES 2008 and the same thing happened for those in the 2009.⁵⁴⁵

Moreover, the medicines suggested to treat the diseases within the guides are generics, and most are to be found within the *Formulario Nacional de Medicamentos Esenciales* (National Chart of Essential Medicines).⁵⁴⁶ This chart was created by the *Código Sanitario* (Sanitary Code) in its Article 100, stating that “... The Ministry of Health, previous technical report from its Technical Regulation Units, will approve a National Chart of Essential Medicines to **supply the country’s needs**. This Chart will specify the pharmaceutical form and dosage of the pharmaceutical product and it will also describe the use, limitations and side effects of those products...”⁵⁴⁷ Generally, the medicines contained on the countries’ national lists of essential medicines are listed by the name of their active ingredient, and in their generic versions, since for most of these patent protections have already expired.

Accordingly, the Central de Abastecimiento – The Central Procurement Office (hereinafter CENABAST) acts as a government body channelling the public health sector’s demands and standardises acquisition processes to ensure the availability and affordability of those essential medicines within the National Chart. Furthermore, this is a functionally decentralised public service, provided with legal independence and own equity and falls within the Ministry of Health mandate.⁵⁴⁸ Due to AUGÉ – GES requirements, the country needs to ensure either access to generic pharmaceuticals or negotiate low prices via bulk procurement in order to fulfil its obligation to provides access to medicines and those pharmaceutical therapies included in the Plan.

CENABAST within its various roles obtains medicines at accessible prices using an effective and efficient business model; a scale acquisition programme has become the preferred model since 2004. To ensure affordable prices the governmental body prompts competition by public bids, calling providers to make offers and therefore the one that makes the best one, translated in a better

⁵⁴⁵ See further, MINSAL site at:

<www.redsalud.gov.cl/portal/url/page/minsalcl/g_gesauge/piloto2009.html> accessed 14 September 2013

⁵⁴⁶ Chile, Ministerio de Salud, *APRUEBA FORMULARIO NACIONAL DE MEDICAMENTOS*, Decreto Núm. 194, Santiago, 26 de agosto de 2005 <www.leychile.cl/Navegar?idNorma=247938> accessed 14 September 2013

⁵⁴⁷ Article 100, *Código Sanitario de Chile*, Decree N° 725/67 later on modified by Ley N° 20.308 published in Official Diary 27.12.2008

⁵⁴⁸ See further, Article 46 of Decree Law 2.763 creating The Central Procurement Office of the National Health Service System (SNSS)

price of medicines, will win the bid.⁵⁴⁹ By using this method, the government also increases transparency in its purchasing programmes, since all the information is public.

National data reveals that by 2005, the health care expenditure in medicines in Chile represents about 25% from the total sales within the country. CENABAST in 2005 estimated that 85% from the pharmaceuticals purchased for Plan AUGE were of local generic production and only 15% of the pharmaceuticals used were imported.⁵⁵⁰

At this point the question about if the patent system as a whole deters the access to medicines must be raised, as along the study it is intended to analyse whether there are other options to keep on protecting pharmaceutical inventions in developing nations while at the same time granting access to affordable medicines.

4.5.1. National Drug Policy and the Chart of Essential Medicines

Due to the Health Care Reform initiated in Chile in the late 80s, it is possible nowadays to talk about a national drug policy and seeking to complement the AUGE- GES plan the government has been developing new health care strategies and actively taking part in international forums.

One of the Chilean Health Care Reform goals was to bring universal access to health care for its citizens. The health care objectives for 2010 were given in a report by the Ministry of Health where the need to reduce out of-pocket expenditure on medicines and health care in general was stated. Thereafter, financial protection is provided with the intention to limit this kind of expenditure, making health affordable instead of a luxury. The same report highlighted that the access to health care is deterred in many cases due to a lack of financial sources when seeking health care attention, meaning that in many poor countries with a weak public health care system its citizens are deemed to pay out of their own pockets for health care expenses, which may be very costly in many cases.⁵⁵¹ This situation may be one of the reasons for why restraining access to medicines and not only to pharmaceutical patents is highly contended.

A National Drug Policy has been carefully implemented in Chile, since public health and access to proper health care is a matter of the State. During the Lagos government(2000 -2004) a national drug reform was necessary since the one dating from 1996 was not fair enough;; inequalities within the health care system did not grant access to health care or medicines for the whole Chilean population. On 4 April 2004 the Resolution N° 515 abrogated the 1996 National Drug Policy.

⁵⁴⁹ See further, commercial processes <www.cenabast.cl/ingles/proveedores/chilecompra.html> accessed 14 September 2013

⁵⁵⁰ Meriches R, J., 'AUGE el Nuevo Botín de las Farmaceuticas' *El Mercurio* (Julio de 2005) <diario.elmercurio.cl/detalle/index.asp?id={2506c1e6-69b2-4c21-85e0-faa8c79372b3}> accessed 14 September 2013

⁵⁵¹ Ministerio de Salud de Chile, División de Rectoría y Regulación Sanitaria, Departamento de Epidemiología Los Objetivos Sanitarios para la Década 2000 – 2010, Primera Edición, Octubre 2002, at 257<www.redsalud.gov.cl/portal/url/item/6bdb73323d19be93e04001011f013325.pdf> accessed 14 September 2013

This reform includes a 31 page document that is an explanatory tool that analyses the situation in Chile during that time and gives suggestions on areas that needed special attention. In that same year, the Chilean Senate was working to comply with the minimum intellectual property standards settled by the TRIPS Agreement. Furthermore, the tool highlights the importance in having generic pharmaceutical versions that will ensure access to medicines available and it also points out the need to include free medication within those clinical guides and protocols designed to provide attention in the AUGÉ-GES guaranties. The Doha declaration on the TRIPS and Public Health were also taken into consideration by this Resolution, especially when the data concerning the price difference between a generic product and a brand name drug is assessed. Among the recommendations made, the National Chart of Essential Drugs should be updated on average every two years, and mechanisms to ensure access to affordable medicines should be reinforced or redesigned together with the role of CENABAST.⁵⁵²

The report highlighted certain concerns regarding the use and prescription of generics, which basically is the fear by users of using a less effective and poor quality product due to cheap prices. Therefore, the National Drug Policy emphasises developing mechanisms destined to ensure quality, efficiency and good manufacturing processes. Brand loyalty and misinformation on the use of generics could be another reason restraining access to affordable medicines and a barrier for the entry onto the market of those products. Therefore, the government must provide enough information about the substitutability and security of the suggested generics through its national bodies. The issue on a lack of information on behalf of the responsible governmental bodies was raised at the Chilean Senate in its 10° Special Session on the 15 April 2009 by Senator Evelyn Matthei, who assured that due studies on bioequivalence that should have been provided by the National Health Institute – ISP were not available for the public or practitioners.⁵⁵³ This issue will be tackled later on in the study.

The Office of Procurement- CENABAST - adopted a different business model during 2004, as mentioned above. The new model consisted of scale purchase programmes or bulk procurement, enabling it to provide the public health care sector with affordable medicines. This is also a strategy recommended by the World Health Organization (WHO) in its guide on “How to Develop and Implement a NDP-National Drug Policy,” and therefore when reading the Chilean National Drug Policy it is very easy to come across the terminology, concepts, definitions and guidelines provided by this Organization in its attempt to harmonise health care policies.

This WHO guide suggests the use of price control policy, reduction of import duties on essential drugs, generating competition on basis of generic policies prompting generic substitution and good procurement practices among many

⁵⁵² Política Nacional de Medicamentos en la Reforma de Salud, aprobada por Resolución Exenta N° 515 de 2 de Abril de 2004, Ministerio de Salud, at 1 – 31

⁵⁵³ Sesión 10, Especial del Senado de Chile, Análisis de la Situación Farmacéutica en Chile, from the 15April, 2009.Audiovisual Senate session
<www.senado.cl/prontus_audiovisual/site/artic/20090415/pags/20090415090512.html>accessed 14 September 2013. The ISP shall require bioequivalence studies of those generic products applying for a marketing approval.

other strategies to increase the affordability of medicines.⁵⁵⁴ Moreover, bulk procurement seems to be one of the most efficient methods, or at least seems to be, working for Chile, since on average this country has the lowest medicine prices Latin America. In 2008, the average was \$4, 73 in Chile, whereas the average in Latin America was \$8, 50 according to the Cámara de la Industria Farmacéutica de Chile – The Chilean Pharmaceutical Chamber (hereinafter CIF Chile) and FIFARMA.⁵⁵⁵ In the same press article, CIF-Chile highlights that the low prices are due to the free market policies being followed in the country and that there is practically no intermediary between the producers and the pharmacy.

One could think that a price control policy is used in Chile to regulate the pharmaceutical market, but it was not until 2009 that the Chilean Senate started suggesting that there should be some kind of price control policy for certain medicines.⁵⁵⁶ A project was submitted to the Senate to consider further regulation for the pharmaceutical industry, but at the 14^o Ordinary Session from the 5 May 2009, the Senate rejected the agreement project. Hence, no price control policy was or is enforced so far in Chile.

Following the recommendation made by WHO, the Chilean National Chart of Medicines contains a wide variety of essential medicines that must be available within the Chilean territory, but all of these are listed under their active component or generic name and not under any brand name product or patented drug. The Supreme Decree N° 466 in its Article 92 used to establish that those medicines included within the National Chart were to be available in their generic version or its brand name version; and the Supreme Decree N° 264/2003 Article 4, establishes the duties of the Health care authorities' in enforcing every legal mechanism available to ensure the availability of those essential medicines in Chile.⁵⁵⁷ By interpreting those articles, and in connection with the Doha Declaration on Public Health, that allows countries to make use of those flexibilities available in the TRIPS Agreement to deal with national emergencies, it could be assumed that if an innovative medicine is needed to provide treatment for any of the GES diseases that become a national emergency, then a compulsory

⁵⁵⁴ World Health Organization, *How to Develop and Implement a national drug policy* (Second Edition, 2001) 1-83

⁵⁵⁵ El Mercurio, 'Carta: Precios de Medicamentos' (27 July 2008)
<www.cifchile.cl/detalle_not.php?id=37>

⁵⁵⁶ Press release, Colusión de Farmacias: Comisión de Salud le propondrá al Senado trabajar en conjunto con el Ministerio sobre la material, in Senado de Chile, Departamento de Prensa, Valparaíso, 14th April, 2009

⁵⁵⁷ Decreto Supremo N° 466 de 31 de Diciembre de 1984, Artículo 92: "... Drug stores shall keep in stock at list those pharmaceutical products listed within the National Chart of Medicines ... those pharmaceuticals might be generics or its similar in the brand name version..." This article was eliminated in 2010 by Decreto 22 de 19 de Febrero de 2010, the new Decree in its Article 93 highlights that drug stores shall have in stock those pharmaceutical products within the National Chart and the same article provides a list of the active components/generic medicines
<www.leychile.cl/Navegar?IdNorma=1011155&idParte=8885599&idVersion=2010-02-19>
accessed 14 September 2013

licence could be sought by the Chilean Government if the medicine were to be patented within the country.⁵⁵⁸

On the one hand, nothing specific is highlighted within the Chilean legislation regarding the patentability or non-patentability of those medicines included in the National Chart, but on the other hand there seems to be various ways to reach the exception to avoid the patentability of a needed pharmaceutical; either by making use of the TRIPS flexibilities or by enforcing the national legislation or public health care policy. According to the articles quoted above and Article 51 part 2, from the Ley N° 19.996, national emergencies, public health crises and public non-commercial use among other situations are ground enough to pursue a compulsory license in Chile.⁵⁵⁹ WHO in its attempt to harmonise health care policies and to help improve health care –access to medicines for all has developed guidelines regarding the implementation and use of traditional medicines within the national drug policies in many countries.

The Chilean Ministry of Health published a book containing 103 herbal medicines or plants used for biopharmaceuticals in its attempt to provide access to alternative ways for health care. Nowadays homeopathy is recognised in Chile as a form of alternative or complementary therapeutic treatment. According to the WHO, in its Publication on the Legal Status of Herbal Medicines, in 1992 Chile provided protection or regulation for traditional medicines within Law N° 19.253, but when searching for that legislation at the Library of Congress database the only legislative piece that pops up is the one creating the commission for the protection of indigenous communities. Furthermore, the WHO Medicine Strategy 2004-2007 proposes the use of traditional medicines (TM) and complementary and alternative medicines (CAM) as an integral part of the health care system. Therefore, it is suggested to create and implement a legislation regulating the use and protection for traditional plants.⁵⁶⁰ Chile became a signatory of the UPOV convention in 1995; therefore, new plant varieties have been protected in Chile since that time.

4.5.2. Should Essential Drugs be Patented?

The access to essential medicines is a highly controversial issue, as explained and defined within the Introductory Chapter. The Doha declaration on the TRIPS and Public Health states and highlights the need to recognise the gravity of public health matter within a globalised world many times, and therefore, flexibilities for those least developed and developing nations were drawn in the agreement.

Flexibilities such as the use of compulsory licences, parallel imports for countries with no manufacturing capabilities, non-commercial use, subject patentability exemptions and patent exemptions are among the choices in addressing the

⁵⁵⁸ See further, The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2, 14 of November 2001

⁵⁵⁹ Ley N° 19.996, Enacted on 05 February, 2005; Article 51.- the decision on a compulsory licence will proceed within the following cases: ... 2) When public health, national security, public non commercial use, or national emergency and other extreme emergency situations, ruled by the competent authorities justifying the use of such licences

⁵⁶⁰ WHOM Strategy, *WHO Medicines Strategy 2004–2007: Countries at the Core*, World Health Organization, WHO/EDM/2004.2

solutions for a health care crisis. Nonetheless, the use of e.g. compulsory licencing under the TRIPS Agreement provisions and Paragraph 6 from the Doha Declaration could be proven costly and unviable as suggested by some scholars.⁵⁶¹ Therefore, further incentives need to be developed to address health care crises in least developed countries.

Prior to the TRIPS Agreement, countries had the liberty on deciding whether or not to protect pharmaceutical products and processes, which could be considered as a shield to protect essential medicines. However, later TRIPS Article 27.1 established that patents shall be available for any inventions, whether products or processes,⁵⁶² and pharmaceuticals could no longer be excluded from patent protection except if they fall within the scope of the 2nd part of the article. This states not granting a patent to an invention in such circumstances so as to protect public order and health among other things is justifiable; moreover, therapeutic and surgical methods to treat humans and animals are also to be excluded from patentability if it is required.⁵⁶³

Arguably, free trade agreements constitute a barrier for access to medicines due to higher levels of intellectual property protection, but objectively the TRIPS agreement brought to the spotlight this difficulty on its own by allowing pharmaceuticals to be patented.

When discussing access to essential medicines, should this be understood in the light of the TRIPS Agreement definition or should it instead be interpreted in light of the Model List of Essential Medicines given by WHO? Or is there a difference between interpretations? The questions arise from the fact that the medicines listed within the list of essential medicines are all done so according to their active ingredients and not by any brand name. So, if the lists are generic versions and active ingredients, should not the issue of essential medication be addressed towards creating new incentives to guarantee access to innovative patented drugs?

Chile is characterised as a progressive state along with other nations moving towards development. Before becoming part of WTO, Chile had already by 1991 reformed its industrial property legislation, and in that reform patents for pharmaceutical products were included. The situation then was quite delicate as the country was overcoming a period of military dictatorship, but this period was also characterised by having progressive views.

4.6. Summarising the Chilean context

Both intellectual property rights and public health (access to medicines) are priorities for the Chilean Government. Adapting its IP law to comply with international commitments, while at the same time strengthening the public health policies, are significant improvements within the geographical areas.

⁵⁶¹ Lucyk, S., 'Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement' (2006-2007) 38 *Ottawa Law Review*, at 191

⁵⁶² Article 27(1) from TRIPS Agreement

⁵⁶³ Article 27(2) and (3) from the TRIPS Agreement

The process is not free of controversy, and some challenges were identified in the analysis. For instance, Chile remains on the Priority Watch List of the Office of Trade Representatives in the 301 Report due to inconsistencies when enforcing intellectual property rights, among other reasons. This could eventually lead to sanctions from its trading partner.

Regarding public health and access to medicines FIFARMA highlighted that the responsibility of providing adequate health care cannot rely solely on the affordability of medicines due to low prices. There are many issues concerning health care, and many actors working together to achieve a highly efficient system. This view is complemented in the case of Chile, with the report by the Ministry of Health on the expected goals for 2010, when describing a health care system that relies on a financial system based on good taxation policies and where social insurance becomes mandatory for its nationals. Another contended issue in Chile regards the possibility of having substitutes for the current pharmaceutical products, since this could increase competition between different producers to reduce the prices of the medicines.

‘Free competition’ among the pharmaceutical industry in Chile did not seem to have worked out as originally envisaged, given that small chains were not able to compete with the prices provided by larger drug store chains. So far, Chile relies on bulk procurement to obtain reduced prices for the needed medicines, in Plan AUGE, and close cooperation with the WHO to maintain high standards of health coverage.

In terms of intellectual property rights, Chile’s negotiating the FTA with United States does not come either as a surprise or coincidence. This trend was initiated as early as 1996 when a Free Trade Agreement with Canada was signed and a provision on IPR’s were included.⁵⁶⁴ Along with the development of the Chilean economic and political growth several trade agreements have been signed with different countries, and within those negotiations different IPR provisions were included. Thus far, the national IP law has been modified to comply with the provisions settled within the U.S.-Chile FTA amid reluctance because specifically test data protection and extending the term of protection were perceived as potentially disruptive for access to medicines in Chile.

⁵⁶⁴ See Roffe, P., ‘Bilateral agreements and a TRIPS-plus world: The Chile-USA Free Trade Agreement’ (October 2004) Quaker International Affairs Programme - TRIPS Issue Paper 4

5 INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES IN VENEZUELA

Political views highly influence the way a society behaves. Moreover, legislative policymaking often revolves around a single idea or a single scenario. This is the case of countries like Venezuela, where pharmaceutical patents and IPRs in general are deemed capitalist interests that are by all means against social interests and needs. The economical rationale behind protecting IPRs has not been denied; nonetheless, the fact that these rights are foreseen within the human or fundamental rights chapter within the political constitutions of several developing countries has contributed to creating a balance of rights dilemma between intellectual property rights and public health.

Venezuela has a long democratic tradition with an economy based mainly in oil. The country has ratified several bilateral and multilateral agreements with different trading partners. Among the most important agreements are the ones with the Andean Community of Nations, MERCOSUR and WTO since by ratifying the agreements with these Organisations Venezuela also became a Member Country.

After overthrowing, in 1958, the dictator Marcos Pérez Jiménez Venezuela began enjoying, in 1959, freedom of speech together with other prerogatives characteristic of a democratic regime. Later on, in 1999, President Hugo Chávez was elected, and even when his policies intended to fix the prevalent economic problems, Chávez ended up implementing similar policies to those despised by him only to accentuate social warfare, inflation, corruption and impunity among others. Accordingly, the oil production in Venezuela has significantly decreased within the past 14 years, thereafter, giving an advantage to the other OPEC Member Countries to increase their levels of productivity.

Intellectual property rights have been safeguarded in Venezuela since as early as 1842, when the specific legislative framework sought to protect inventions in general. Already at that time, patents were available not for pharmaceutical patents per se, but also for industrial purposes. In 1955, patents, trademarks and other rights were regrouped in a single IPR legislation that later on, in 1992, became unified through the Andean Community Sub regional Organisation. It is important to highlight that Venezuelan IP Law distinguishes between intellectual property rights and industrial property rights; the first ones are mainly related to copyright, and the second ones refer to patents, trademarks, utility models and geographical indications.

No one could have had forecasted how well this Regional Integration was going to work, if at all. Scholars have pointed out the relevance of the Andean Justice Tribunal for the region's intellectual property law development. Between 1987 and 2007 the Court gave 1303 preliminary court rulings related to intellectual property law from a total of 1338 cases; hence all of these rulings were binding decisions for all the Member States. Unfortunately, Venezuela withdrew from the Andean Community in 2006 and from then the national intellectual property legislation should have been modified in accord to the minimum standards of protection settled within the TRIPS Agreement.

At the beginning of the research a couple of challenges were identified leading to question whether or not the pharmaceutical patents granted in Venezuela have had a significant impact on the access to medicines, and whether or not the country would be in breach of the obligations undertaken as a WTO Member State if it re-enacted the IP legislation from 1955.

This chapter will be structured in a manner so that even when the main focus is intellectual property rights and public health, the chapter still reflects the legislative changes from the pre-constitutional reform era to the era post-constitutional reform from 1999. For clarity within the analysis the reader will be presented with three sections: the first analyses the intellectual property rights legislation and related institutions; the second provides a public health care system overview; and the third addresses the link between pharmaceutical patents and universal coverage (access to medicines) as envisaged within the Constitutional framework from 1999, and other regulatory provisions related to medicines per se. The findings of the analysis will be preliminarily assessed within the remarks and the dissertation's general summary.

For the purpose of the study, the term intellectual property rights have been used as a synonym from industrial property rights. Within the Venezuelan IP law, there is a theoretical distinction between intellectual property rights and industrial property rights. The first ones mainly refer to copyright law, whereas the second one refers to patent, trademarks and industrial drawings, meaning those creations with industrial and/or commercial applicability.⁵⁶⁵ Both fields are constitutionally protected, but Ley para la Propiedad Industrial (hereinafter IP Law from 1955) only regulates the aforementioned rights; and a special law is meant to regulate copyright and author's rights. Hence, differentiating between intellectual property rights and industrial property rights.

5.1. Intellectual Property Rights in Venezuela

The IPR system in Venezuela has been inspired or influenced by foreign systems, and in particular the American and French systems worked as a referential framework to shape the first intellectual property law, in 1878, in Venezuela. This legislation underwent several reforms during 1882, 1927 and 1955.⁵⁶⁶

Given that Venezuela is a Member Country of both WTO and the Andean Community, the country was also required to reform the IP law from 1955 to comply with the new international and minimum standards of protection. Thus, patents for medicines, chemical formulas and compounds and alike were not possible.⁵⁶⁷

⁵⁶⁵ Rondón de Sansó, H., 'El Concepto de la Propiedad Intelectual en el Régimen de la Constitución de 1999' (2005) 153 *Boletín de la Academia de Ciencias Políticas y Sociales*, at 396

⁵⁶⁶ Morles Hernández, A., (ed.) 'Las Patentes de Invención' in *Curso de Derecho Mercantil: Introducción, La Empresa, El Empresario* (Tomo I, Universidad Católica Andrés Bello, Caracas:Venezuela -2004) at 311

⁵⁶⁷ Ley de Propiedad Industrial, Publicada en la Gaceta Oficial N° 24873 del 14 de Octubre de 1955. Artículo 15. "Patents are not available for: 1.- ... the medicines of every kind, pharmaceutical compounds and their preparation processes, chemical combinations and reactions" Original text in Spanish, translation provided by the author.

Some years later the Andean Community⁵⁶⁸ enacted a binding decision reshaping the IP system, Decision 344, that allowed Venezuela to comply with the aforementioned standards by implementing the Andean decision into their internal legislation. Decision 344 was later on substituted by Decision No. 486, which settled IPRs' standards accordingly. In 2006, Venezuela withdrew from the Andean Community, and thereafter concerns encompassing the legal framework to protect intellectual property rights arose. Venezuela, as a former Andean Community Member, kept on applying the Decision 486 as a referential framework to revise patent applications and other intellectual property right claims. The country should have reformed its internal legislation so as to comply with the TRIPS agreement, but instead re-enacted the IP Law from 1955. The decision to re-enact the IP law from 1955 by the Servicio Autónomo de la Propiedad Intelectual –SAPI (Patent Office) in a notice dated 12 September 2008 has been a controverted issue. This controversy will be analysed within the title assessing the implications for Venezuela from its membership in the Andean Community of Nations.

In Venezuela, the Servicio Autónomo de la Propiedad Intelectual (herein SAPI – Venezuela's Patent Office- is a body ascribed to the Ministerio del Poder Popular para el Comercio – Ministry of Commerce-, and therefore this is the entity responsible for the protection and registration of intellectual property rights.

SAPI was created by the Presidential Decree number 1768 on 25 March 1997 and published in *Gaceta Oficial* No. 36.192 on 24 April 1997. At that time the Ministry of Commerce was the Ministry of Commerce and Production, but later on was renamed to Ministry of Commerce. SAPI began to operate on 15 May 1998 in accord with Resolución Ministerial N° 054 del 07 de abril de 1998, published in *Gaceta Oficial* N° 36.433 del 15 de abril de 1998.⁵⁶⁹

Scholars have highlighted that only with a new IP Law would it be possible to derogate a transitional regime. Thus a new doubt emerges precisely with the Parliament approval of a Law for Science, Technology and Innovation (Ley Orgánica de Ciencia, Tecnología e Innovación - LOCTI), because of the conflict of competences brought into the spotlight. It has been seriously questioned whether or not the new legislation derogates the previous one. In the first instance, this law finds its basis in Article 98 of the Constitution of the Bolivarian Republic of Venezuela,⁵⁷⁰ where not only IPRs constitutionally protected, but also in the light

⁵⁶⁸ CAN see: Who are we? Andean Community - Brief history, is a sub regional integration community of countries (Bolivia, Chile, Colombia, Ecuador and Peru), created in 1969 through the Cartagena's Agreement <www.comunidadandina.org/ingles/quienes/brief.htm> accessed 14 September 2013

⁵⁶⁹ SAPI "Breve reseña histórica" <www.sapi.gov.ve> accessed 15 November 2011

⁵⁷⁰ Constitución de la República Bolivariana de Venezuela de 1999. Publicada en *Gaceta Oficial* Extraordinaria N° 5.453 de la República Bolivariana de Venezuela. Caracas, viernes 24 de marzo de 2000 "Article 98° Cultural creation is free. Including the right to invest in, produce and disseminate literary, scientific, technologic and humanistic work, as well as legal protection for the authors' rights in their works. The State recognises and protects intellectual property rights in scientific, literary and artistic works, innovations, indications, trade names, patents, trade marks, slogans according with the conditions and exceptions established by law and in International treaties executed and ratified by the Republic in this field."

<www.unhcr.org/refworld/category,LEGAL,,,VEN,4c45ad8b2,o.html> accessed 20 January 2012

of the same Article the State has the responsibility of promoting innovation of technology.⁵⁷¹ Articles 27 and 28 of the LOCTI with great vagueness rule over “previous conditions of ownership and IP protection”, and therefore by virtue of those articles this new entity created to promote technological innovation could be overlapping the competences of the Popular Ministry of Light Industries and Commerce, which initially managed these issues through SAPI.

This first part analyses Venezuela’s intellectual property legislative framework, starting with an assessment of the Constitutional approach towards IP rights, followed by an overview to the IP Law from 1955. The analysis will continue with an overview of the Andean Community system, implications for the country, the legislative challenge as a consequence from Venezuela’s withdrawal from the Andean Community and the new challenges derived from the membership into MERCOSUR. The present structure aims to allow better understanding over the differences between the IP regime while Venezuela was an Andean Community member and the current system.

5.2. Constitutional Approach to Intellectual Property Rights: In Accordance with 1999’s Constitutional Reform

Before analysing in depth the constitutional provisions granting protection for intellectual property rights in Venezuela, it is important to dedicate a few lines to the legal sources governing these rights.

The legal hierarchy starts with the political constitution at the top of the pyramid, followed by norms with legal rank –those implemented in a direct and immediate manner, such as formal laws and government acts – and at the bottom of the pyramid are those laws with a sub-legal character.⁵⁷² Within the Constitution currently in force, in Venezuela, there are four particular articles to take into consideration to understand the status of both IP rights and standards settled in international and integration treaties.

Intellectual Property rights are constitutionally protected in Article 23 and 98 under Title II - Chapter I is devoted to duties, human rights and guarantees,, and Chapter VI to establishing cultural and educational rights. The Constitution, as the primary source of law, grants supra constitutional⁵⁷³ rank to those international treaties, conventions and agreements ratified by Venezuela within the field of human rights.⁵⁷⁴ This implies direct and immediate application as highlighted in Article 153. Furthermore, the State recognises and protects

⁵⁷¹Ley Organica de Ciencia, Tecnología e Innovación (LOCTI) still to be announced in the Oficial Gazette

⁵⁷² Rondón de Sansó, H., ‘El concepto de la Propiedad Intelectual’ at 399

⁵⁷³ Supra National within the Venezuelan context means that an international regulation has a higher rank than the constitution itself, namely the Declaration on Human Rights

⁵⁷⁴ Constitución de la República Bolivariana de Venezuela de 1999. Article 23 “Treaties, pacts and conventions relating to human rights which have been executed and ratified by Venezuela, have constitutional rank and prevail over national legislation as long as they contain provisions concerning the enjoyment and exercise of such rights that are more favorable than those established by this Constitution and the laws from the Republic, and are of immediate and direct application by Courts and other organs from the Public Power.”

<www.unhcr.org/refworld/category,LEGAL,,,VEN,4c45ad8b2,o.html>accessed 20 January 2012

intellectual property rights –such as inventions- accordingly with the conditions and exceptions established by law and in International Treaties executed and ratified by Venezuela.⁵⁷⁵ Also falling within the human rights category, is the property right provided in Article 115. Given that, patent rights grant exclusive rights to right holders, withholding property rights over their inventions. Despite finding a general definition of property in the constitution, the exclusivity right is not stressed.⁵⁷⁶ One of the linking factors between the property right per se and intellectual property rights are the limitations foreseen by the IP Law from 1955, i.e. expropriation due public interest. This theory will be assessed in the heading analysing the aforementioned limitation.

Even though intellectual property rights are included within the human rights chapter in the Constitution, due to the parameters settled in both Article 27 from the Universal Declaration of Human Rights and Article 15 from the International Covenant on Economic, Social and Cultural rights, highlight the scope of the freedom to create. This extends to the right to “invest financially” as stated in Article 98. Venezuelan scholars have suggested misplacement in the use of that terminology, stressing the fact that these are generally economical activities and therefore the word “invention” should have been placed instead.⁵⁷⁷

Moreover, if Article 98 is analysed in detail, two parts can be identified. The first one regards cultural creations as free and immediately the elements of that freedom to create are described, namely the rights to invest, the right to produce and the right to disseminate creations. In the second part, intellectual property rights are recognised and protected by the State, namely scientific, literary and artistic works, inventions, innovations, denominations, indications, patents, trade marks and slogans. Another interesting fact is that despite the Venezuelan law differentiating intellectual property rights from industrial property rights, Article 98 from the Constitution conglomerates all immaterial rights under the scope of intellectual property rights.⁵⁷⁸

The constitutional scope of protection in Venezuela is extended to indigenous collective intellectual property rights foreseen in Article 124. by safeguarding traditional knowledge by constitutionally prohibiting others from obtaining patent rights. In the light of this provision, traditional knowledge, indigenous technologies and inventions are regarded as property, specifically collective property that possibly grants collective benefits to the community. Hence, the main characteristics embedded in property rights -namely the right to use, enjoy and dispose of – are expressly laid out when establishing indigenous IP rights, whereas this is left to assumption within the context of Article 98.

Even though the property right per se will be addressed later on, it is important to stress that Article 115 does not follow the general structure in all constitutional provisions, which is first stating and then settling the definition. In this case it is

⁵⁷⁵ Article 98, Constitución de la República Bolivariana de Venezuela de 1999

⁵⁷⁶ Rondón de Sansó, H., ‘El Concepto de la Propiedad Intelectual’ at 390

⁵⁷⁷ Fariñas Díaz, J., ‘La Protección Constitucional de la Propiedad Intelectual en Venezuela’ (2009) 12 *Revista de Propiedad Intelectual*, 10-33 at 18. See also, Brewer Carías, Allan R. *La Constitución de 1999, con el texto oficial de la Constitución Gaceta Oficial N° 5453 Extraordinaria del 24-3-2000* (Editorial Jurídica Venezolana, Editorial Arte, 3rd Edition, Caracas, 2001) at 47

⁵⁷⁸ Fariñas Díaz, J., ‘La Protección Constitucional’ at 18

only mentioned property, but its meaning is not described,⁵⁷⁹ leaving aside the fact that there three types of property in Venezuela –private, public and collective.

Furthermore, Article 153 establishes the position from the Government in relations to international treaties and conventions;; in general terms those in virtue of integration organisation will have direct and preferred implementation within national law. This is especially relevant, given that Venezuela denounced the Cartagena Agreement in 2006, hence, controversies on the validity of the IP Andean Community framework governing until that date emerged. This will be analysed within the Andean Community context further below.

5.3. Current Intellectual Property Legal Framework

Within the legal hierarchy, as a formal law, the IP Law from 1955 should be analysed next. In Venezuela, Ley de Propiedad Industrial of 2 September 1955, published in Gaceta Oficial N° 24.873 from 14 De Octubre de 1955, currently regulates the intellectual property system. It comprises 15 chapters, general, transitional and final provisions. Given the focus of this study, only the chapter and provisions relevant to patents will be taken into consideration.

This law has some characteristic features to look at, of which among them are the topics related to patentable subject matters –inventions, discoveries, improvements and introduction of inventions - property rights and the right to claim inventions. In other words, who is to be recognised as the patent holder, the inventor or the one filing the patent application. According to Article 3° from the Patent Law from 1955 the property of the invention belongs to the one to whom the patent certificate has been issued.⁵⁸⁰ In this respect, the administration forgoes the right to verify who the real inventor is; most likely the only way for him/her to claim ownership will be through a judicial action,⁵⁸¹ even though the Law specifically requests that the “real inventor” claim the patent protection.

It has been suggested that Venezuela’s law differentiated between the patent right to exclude others and the rights emerged from the invention per se given that a patent could not be granted unless this invention met the legal requirements. However, the absolute right came after the right was granted.⁵⁸²

In a sense, the IP law in Articles 5 and 59 (1) establishes as the original/real inventor the person entitled to patent ownership. Hence, the inventor’s name, domicile and nationality are to be specified within the application claiming patent rights.⁵⁸³ In other words, the inventor carries the burden of prove given that the

⁵⁷⁹ See Fariñas Díaz, “La Protección Constitucional” and See also Rondón de Sansó, “El Concepto de la Propiedad Intelectual”

⁵⁸⁰ Ley de Propiedad Industrial, Gaceta Oficial N° 24.873, Article 3° “The Law presumes as the invention owner, ..., the person to whom the patent certificate has been registered for” Original text in Spanish, translation provided by the author. Artículo 3° “Se presume que es propietario de un invento, ..., la persona a cuyo favor se haya hecho el correspondiente registro”

⁵⁸¹ Sansó, B., and Rondón de Sansó, H., *Estudios de Derecho Industrial* (Universidad Central de Venezuela, Facultad de Derecho, Caracas: Venezuela - 1965) Vol. XXXV, at 7

⁵⁸² *Ibid* at 9

⁵⁸³ See further Article 58 and 59(1) IP Law 1955

law in part (C) requires certification attesting that the applicant is the real inventor of the invention. Contradictorily, it has been argued that the administration is careless in either verifying or elaborating further over this matter.⁵⁸⁴

Another interesting feature regards patentability requirements that can be summarised as new, defined and useful.⁵⁸⁵ This, read in conjunction with Article 15 (9°) from the Law, could be interpreted as meaning that “new” refers to “novelty”, which is required and defined in modern legislation within the scope of the state of the art.

This system is regarded as a declarative system, given that rights are born in the same moment as the inventive idea, and thus it becomes the State’s duty to grant protection to the inventor by issuing the patent certificate.⁵⁸⁶

5.3.1. The Patent Office (SAPI) Competences

Everything related to intellectual property rights are to be taken before the Registro de la Propiedad Industrial, nowadays Servicio Autónomo para la Propiedad Industrial (Hereinafter SAPI). This entity is responsible for the registration and grant procedure of IP rights.⁵⁸⁷ Therefore, IP law Chapter V contains all the relevant provisions defining this entity’s competences, qualifications to become Registrar, publicity, Registrars attributions and administrative remedy against this entity’s decisions.

From the ten (10) articles contained in this chapter, four (4) of them are of particular interest. Article 38 establishes the conditions to become the Registrar, which are basically summed up as being a lawyer and that this position is of free removal by the president.⁵⁸⁸

Within the many attributions given by law to the registrar, two are worth mentioning. Article 40 highlights the duty in providing information of public character to anyone who requests them, except those patent files requested to be kept confidential in accord with legislative provisions.⁵⁸⁹ Secondly, the Registrar

⁵⁸⁴ See further Article 59 (c) from Ley de Propiedad Industrial, See also Sansó, B. at 9

⁵⁸⁵ Article 14 from Ley de Propiedad Industrial, Patentable subject matters (1°) “products that are new, defined and useful” Original in Spanish, translation provided by the author Artículo 14 Pueden ser patentados: (1°) “todo producto Nuevo, definido y útil”

⁵⁸⁶ Uzcátegui Urdaneta, M., *Invención y Patente de Invención en el Derecho Venezolano* (Ed. Caus, Caracas-Venezuela, 1965) at 97

⁵⁸⁷ Artículo 37 from Ley de Propiedad Industrial, “Everything related to industrial rights will be governed by an office named Registro de la Propiedad Industrial” Original text in Spanish translation provided by the author. Artículo 17 “Todo lo relativo a la Propiedad Industrial estará a cargo de una oficina que se denominará Registro de la Propiedad Industrial”

⁵⁸⁸ Article 38 from Ley de Propiedad Industrial, “Patent Office Registrar shall be a lawyer who will be freely elected and removed by the President through Ministry of Commerce” Original text provided in Spanish translation provided by the author. Artículo 38 “El Registrador de la Propiedad Industrial deberá ser abogado y de la libre elección y remoción del Ejecutivo Nacional, por órgano del Ministro de Fomento”

⁵⁸⁹ Article 40 from Ley de Propiedad Industrial, “Is the Registrar’s duty to show all interest parties all patent files, office books, resolutions, etc, available within the Office free of charge ... Public

also becomes an administrative judge, in the sense that he is designated to acknowledge and decide over oppositions presented before SAPI.⁵⁹⁰ Thirdly, the Patent Office archives shall remain open to the public for a period of four (4) hours per working day.⁵⁹¹

And fourthly, in light of Article 43 resolutions from the Registrar about registrations, oppositions or objections can be appealed before the Ministry of Commerce within five (5) working days from the notification date to the interested party.⁵⁹²

The legislation also regulates in its chapter VI everything related to registration certificates, patent fees and claim taxes. All of these have been adapted to the current credit unit value in Aviso Oficial N° 17, published within Boletín N°512.⁵⁹³

Moreover, IP agents are also regulated. This figure allows interested parties to do all necessary formalities before SAPI to request patent protection for an invention without having to do it him/herself exclusively. Therefore, certain requirements are to be taken into consideration before qualifying as an IP agent. Basically, a person must either be an economist or a lawyer and he/she shall be registered within the Registration Book for IP Agents.⁵⁹⁴ Further provisions suspending IP agents are also stated, and perhaps the most important one related to the Registrar's competence to sanction agents *de oficio*.⁵⁹⁵

disclosure is limited to patent files requested to remain confidential accordingly with legislative provisions"Original text in Spanish.Translation, modifications and highlights provided by the author. **Artículo 40** " El Registrados tiene el deber de hacer mostrar dentro de la Oficina, a todo aque que lo pida, libros, indices, documentos, expedients, actas y planos que existen en la Oficina, sin poder cobrar ningún emolumento por este trabajo nip or permitir que los solicitantes saquen las compias simples que deseen. Se Exceptúan de esta disposición los expedients de patentes de invención que se hubieren mandado a reservar conforme a la Ley."

⁵⁹⁰ Sansó, B., Las Patentes de Invención, at 27

⁵⁹¹ Article 41 from Ley de Propiedad Industrial, " SAPI's archives shall remain open to the public for a period of four (4) hours per working day"Original text in Spanish, translation provided by the author. Artículo 41 from Ley de Propiedad Industrial "El Archivo de Registro de la Propiedad Industrial estará abierto y a la disposición del público durante cuatro (4) horas por lo menos de cada día hábil"

⁵⁹² Article 43 from Ley de Propiedad Industrial, "All resolutions from the Registrar regarding registration, objections or oppositions, shall be appealed before the Ministry of Commerce, within five (5) working days from the notification date to the interested party" Original text in Spanish, translation provided by the author. **Artículo 43** "De toda resolución del Registrador sobre registros, objeción u oposición, se oirá apelación por ante el Ministerio de Fomento, dentro de los cinco (5) días hábiles contados a partir de la fecha de la notificación al interesado."

⁵⁹³ SAPI, Aviso Oficial N° 17 "Tasas, Marcas y Patents"

<www.sapi.gob.ve/images/stories/AvisosOficiales/serviciosmarcaspatentes.pdf>accessed 21 November 2011

⁵⁹⁴ Article 52 from Ley de Propiedad Industrial To become an IP agent is necessary to: 1° Be an economist, or a lawyer...; 2° Shall be properly registered within IP Agents Book" Original text in Spanish, transpation provided by the author. Artículo 52. Para ser Agente de la Propiedad Industrial se requiere: 1° Ser abogado o economista ...; y 2° Estar debidamente inscrito en el Libro de Registro de Agentes de la Propiedad Industrial que a tal efecto lleve la Oficina."

⁵⁹⁵ See further Parágrafo Primero – Artículo 53, Ley de Propiedad Industrial

As previously mentioned, an official notice (Aviso Oficial) informed the public about patent and trademark fees. Therewith, Chapter VIII regulates and gives public instrument character to those Avisos Oficiales and Boletines de la Propiedad Industrial – Official notices and IP Journals - from the patent office.⁵⁹⁶

In light of these provisions, two functions are embedded within the IP Journal. On the one hand, that of informing third parties over relevant matters dealing with the Patent Office per se, granting or patent denial and claims ultimately allowing interested parties to formulate opposition when his/her rights could be infringed. And on the other, the main function from this IP Journal is to give authenticity to those acts and resolutions contained in it, while at the same time informing the public about deadlines to comply with certain acts and procedures.⁵⁹⁷

5.3.2. Types of Patents

The Venezuelan patent law distinguishes among product patents, “introduction of invention or improvement patent”, and revalidation patents. The first ones, as described above, comprised products (others); within the second ones the legislative text seems to differentiate between an improvement and introducing an invention, but is not clearly defined; and, the third one regards those inventions already protected abroad. However, in practice it is not certain whether or not all of these are granted.

Chapter II dedicated to “Patents” in Article 5 does not only set forth the types of patents and content, but also highlights rights conferred by each kind. In this respect, *Patents for inventions, improvements, model or industrial drawings* and those *introducing an invention or improvement* grant to patent holders exclusive rights to make use, produce or industrially process the patented subject matter within the terms and conditions given by Law. However, the same article provides that invention or improvements introductory rights are not exclusive per se since these cannot prevent third parties from importing the product or improvement introduced by them into the country.

Given that *introductory patents* do not grant exclusive rights,⁵⁹⁸ these have been approached as inventions that required patent protection in Venezuela before commercialisation despite being protected abroad.⁵⁹⁹

⁵⁹⁶Article 54 from Ley de Propiedad Industrial “All publications envisaged within this law, shall be done through IP Journal as body from the Patent Office. All samples are binding public instruments.” Original text in Spanish, translation provided by the author. **Artículo 54** “Todas las publicaciones previstas en la presente Ley, deberán hacerse en el Boletín de la Propiedad Industrial que es el órgano de la Oficina de Registro. Los ejemplares de este Boletín tendrán fuerza de instrumento público”

⁵⁹⁷ Sansó, B., ‘Las Patentes de Invención’ at 29

⁵⁹⁸ Article 5, Ley de Propiedad Industrial

⁵⁹⁹ Sansó, B., ‘Las Patentes de Invención’ in Sansó, B., and Rondon de Sansó, H., (eds), *Estudios de Derecho Industrial* (Universidad Central de Venezuela, Facultad de Derecho, Caracas, 1965) Volumen XXXV, 1-264 at 16.

In light of Article 5^o the main difference between introductory patents and patents for inventions per se seems to be the scope of protection. One grants exclusive rights and the other one does not.

Revalidation patents are those for which patent protection is granted on the basis of its previous approval abroad provided the term of protection has not expired yet.⁶⁰⁰

Improvement patents are those concerning an invention perfecting the previous invention.⁶⁰¹

Given that there is almost no distinction between revalidation patents or patents introducing an improvement or invention, it has been suggested that the Venezuelan law seemed to create an additional patent category besides the classic ones -patents for inventions and industrial drawings- by introducing within the same enumeration “patent for improvements.”⁶⁰²

Even though a distinction by means of definition is not feasible, it is possible to assume certain characteristics on the basis of the terms of protection and possibilities to have priority in obtaining the patent certificate. Article 9 foresees protection for inventions, improvements, models and industrial drawings for a period between five (5) to ten (10) years according to the inventors wishes; whereas only five (5) years is the term of protection granted to patents for introduction of inventions.

Regarding the term of protection and possibility in obtaining it for revalidation patents, Article 10 is very clear in stating preconditions and terms of protection. In other words, on the one hand patent protection will be granted for those inventions already protected abroad “as long as these meet national legal requirements and that these are not part of the public knowledge” – which leads to another contradiction within the law – and on the other, the term of protection will be for the remaining period of validity on basis of the patent already granted.

Priority rights or to obtain the patent certificate in Venezuela when this has already been granted abroad is given in Article 11. It stresses a timeframe of 12months counted from the date the patent certificate was issued abroad to when it was petitioned before SAPI.⁶⁰³ But what happens if the patent application was submitted after this period? Would the patent then have to wait in the pipeline to be processed? The legislation is not clear on this matter.

Among the patent requirements, even for those products already protected abroad, is the fact that any invention seeking protection cannot belong to the public domain. Furthermore, the IP law from 1955 seems to be vague when dealing with revalidation patents that became part of the public domain. In other words, it is not clear whether or not it is enough for a product to be known in a foreign territory as for the Venezuelan Registrar to denote this fact as also being

⁶⁰⁰ Rondón de Sandó, H., La Decisión 313 de la Comisión del Acuerdo de Cartagena y el Régimen de Propiedad Industrial (Caracas:Venezuela -1993) at 19

⁶⁰¹ Sansó, B., ‘Las Patentes de Invección’ at 15

⁶⁰² Idem, at 16

⁶⁰³ Artículo 11 from Ley de Propiedad Industrial

part of the national public domain;⁶⁰⁴ hence, not granting patent protection on the basis of public knowledge.

Two interesting scenarios are presented in Article 12. First, the original or foreign patent holder is entitled by Law to oppose any patent claims made in Venezuela to introduce its invention or improvement within the following 12 months after the patent has been granted abroad; and if during this time there is such a claim before SAPI. Secondly, if the foreign patent holder submits a patent application to protect its invention or improvement in Venezuela 12 months after this has been granted abroad, and at the same time this one has already been granted to a third party in Venezuela as a “patent for introducing an invention or improvement”, then the original patent holder is entitled to request the certificate’s abrogation. And thirdly, the patent’s office Registrar could give the patent nullity without a separate procedure other than the patent owner petition. Summing up, this article not only gives priority to a certain extent to those inventions or improvements already patented abroad, but also recognises inventors’ legitimate claim over their work by allowing them to request the abrogation of patent certificates without having to start a judicial procedure.

5.3.3. Inventions and Discoveries

Thus far, Venezuela’s IP Law from 1955 does not foresee a definition for either patent or invention, but instead aims to enumerate what does and what does not constitute patentable and non-patentable subject matter throughout Articles 14 and 15.

Despite Article 14 enunciating all patentable subject matters, as suggested above, it in section one also introduces patentability requirements. Hence, every product new, defined and useful could be worthy of patent protection.⁶⁰⁵ Therewith, “new” understood as “novelty” allows any product or industrial drawings not listed within non-patentable subject matters to receive patent protection, as clearly stated in the provision’s last paragraph.⁶⁰⁶

No product meeting the novelty requirement -objective patentability precondition- would be entitled for such protection, meaning that the invention cannot be of either public knowledge or belong to the public domain.⁶⁰⁷ Initially, everything listed within Article 14 shall be patentable as long as it is new, defined and useful. Even when this provision does not assess how the novelty requirement is measured, Article 15(9^o) moves forward in stating that inventions known by the public due to publications or disclosure in printed works or any other form, and those belonging to the public domain due to materialising, distribution and/or displaying it locally or abroad before the patent claim has been submitted, are not patentable.⁶⁰⁸

⁶⁰⁴ Sansó, B., ‘Las Patentes de Invención’, at 16 -18

⁶⁰⁵ Article 14 (1) from Ley de Propiedad Industrial from 1955

⁶⁰⁶ Article 14 in its Only Paragraph emphasises its enunciative character, hence, not restrictive. Given that in general terms anything resulting from human inventive efforts, with the exceptions given by law, can and would be patentable

⁶⁰⁷ Sansó, B., ‘Las Patentes de Invención’, at 16 -18

⁶⁰⁸ Article 15 (9) from Ley de Propiedad Industrial

Following the discussion on patentability, Uzcátegui Urdaneta suggests that inventions are organised according to the objects' nature, procedures and type of invention.⁶⁰⁹ Given the objects' nature, patents are for machines,⁶¹⁰ instruments and appliances.⁶¹¹ In accord with the procedures⁶¹² and defining the kind of inventions this includes improvements,⁶¹³ modifications,⁶¹⁴ new industrial models and design.⁶¹⁵ Another approach suggests Venezuela's IP law categorises inventions according to the products' invention object, procedure, machineries – instruments and spare parts; and discoveries with industrial applicability.⁶¹⁶

Moving on to non-patentable subject matter, Article 15 presents a list of inventions that are not protected despite meeting patentability criteria:

1° drinks and foods, destined for human or animal consumption; all kinds of medicines, medicines pharmaceutical preparations and preparations, reactions and chemical combinations;⁶¹⁷

2° systems, combinations or business plans, speculative, commercial, marketing or of simple fiscal control;⁶¹⁸

3° use or simple use of substances or natural forces even when just discovered;⁶¹⁹

4° products, objects, substances or elements previously known or used for determined purposes, new uses or those simple changes or variations in shape, dimensions or materials originating from those;⁶²⁰

5° know-how or industrial secrets;⁶²¹

6° strictly theoretical or speculative inventions unable to prove defined utility, practicality and industrial application;⁶²²

7° inventions contrary to national law, health or public order, moral and good customs and States security;⁶²³

8° Juxtaposition of already patented elements or that these belong to the public domain, unless these cannot operate independently without using their functionality.⁶²⁴

9° Inventions known in the country due to their publication or that belong to a printed publication or in any other form, or those belonging to the public domain as a result of

⁶⁰⁹ Uzcátegui Urdaneta, M., *Invención y Patente de Invención en el Derecho Venezolano* (Ediciones Casuz, Caracas, 1965) at 29.

⁶¹⁰ Article 14(2) from Ley de Propiedad Industrial

⁶¹¹ Article 14 (3) from Ley de Propiedad Industrial

⁶¹² Article 14 (4) and (5) from Ley de Propiedad Industrial

⁶¹³ Article 14 (6) from Ley de Propiedad Industrial

⁶¹⁴ Article 14 (7) from Ley de Propiedad Industrial

⁶¹⁵ Article 14 (8) from Ley de Propiedad Industrial

⁶¹⁶ Sansó, B., 'Las Patentes de Invención' at 12

⁶¹⁷ Article 15 (1) from Ley de Propiedad Industrial de 1955

⁶¹⁸ Article 15 (2) from Ley de Propiedad Industrial de 1955

⁶¹⁹ Article 15 (3) from Ley de Propiedad Industrial de 1955

⁶²⁰ Article (4) from Ley de Propiedad Industrial de 1955

⁶²¹ Article 15 (5) from Ley de Propiedad Industrial de 1955

⁶²² Article 15 (6) from Ley de Propiedad Industrial from 1955

⁶²³ Article 15(7) from Ley de Propiedad Industrial from 1955

⁶²⁴ Article 15 (8) from Ley de Propiedad Industrial from 1955

their use, sell or publicity inside or outside the country prior to filing the patent application.⁶²⁵

In light of the aforementioned articles, patents for pharmaceutical products are not possible due to public interest, but a patent to manufacture them seems possible. The same is applicable for chemical products –non-patentable- but the industrial process to produce them is patentable.⁶²⁶

Other scholar suggests the rationale behind these prohibitions was strictly considered to avoid abuses on behalf of patent owners i.e. restricting access to medicines. But the prohibition, in his view, turned out to be detrimental because patents are an incentive to promote the country's industrial development. The pharmaceutical industry relies on patents of R&D products destined to improve people's health and lives; and, because there are enough legal means to stop or avoid abuses on behalf of patent owners.⁶²⁷

5.3.4. Public Interest and Patents

Venezuela's IP Law from 1955 addresses two cases where public interest affects patents, but there is no provision dedicated to deal with compulsory or voluntary licences. In the worse case scenario, patent rights will be expropriated by the State when the invention is considered to be of fundamental public interest.⁶²⁸

Analysing the content of Article 4- indirectly leaves open the door for patent holders to grant voluntary licences. This one regards the effects on third parties before rights were registered within the patent office's books.⁶²⁹

The law does not provide further provisions addressing either cases of public interest or public use. Article 20 refers to cases of lapsed patent registration rights, in which inventions will belong to the public domain, and hence, have public use.⁶³⁰

There are certain important issues that need to be analysed in conjunction with Ley de Expropiación por Causa de Utilización Pública o Interés Social (Law for the Expropriation due Public Use or Public Interest - herein LEXP) without falling into a pure administrative law discussion. What is of interest here is to assess, namely, who can expropriate goods, what is to be considered public interest, how are goods affected with public interest, which is the procedure followed and which are the provisions dealing with this matter.

In Venezuela, in accordance with Article 2 LEXP, expropriation is an institution of Public Law that belongs to the National Government, therefore the State uses it

⁶²⁵ Article 15 (9) from Ley de Propiedad Industrial from 1955

⁶²⁶ Sansó, B., 'Las Patentes de Invención' at 13

⁶²⁷ Uzcátegui Urdaneta, M., *Invención y Patente de Invención en el Derecho Venezolano* at 100 -101

⁶²⁸ Article 16 from Ley de Propiedad Industrial from 1955

⁶²⁹ Sansó, B., 'Las Patentes de Invención' at 22

⁶³⁰ Article 20 from Ley de Propiedad Industrial from 1955

to benefit society by taking goods that represent social or public interest.⁶³¹ This action can only be achieved via court ruling and fair compensation.⁶³²

Moreover, goods of public interest have to be defined or highlighted what is to be understood for these. In this respect, Article 3 points out that all kinds of goods destined to provide the Republic with uses or improvements for the general good are to be considered goods of public interest.⁶³³ Although the distinction between immaterial and material goods susceptible to expropriation is given within the legislation, there is no strict mention of intellectual property rights per se. This is why it is believed that expropriation of intellectual property rights can only be achieved via analogy, and the use of Article 62 foreseeing “goods with some artistic value”.⁶³⁴ Moreover, “goods of any kind” could fall within the public interest accordingly to the Constitution’s Article 115.⁶³⁵

Property rights are also governed by the Código Civil (Civil Code – herein CC) Articles’ 545, 546 and public utility in Article 547 CC. Article 545 comprises both

⁶³¹ Ley de Expropiación por Causa de Utilización Pública o Interés Social, Gaceta Oficial N° 37.475, (hereinafter Ley de Expropiación) Article 2 “Expropriation is an institution of Public Law, the State acts in benefit of public use and social interest with the goal of forcing a transfer of goods property or individuals rights into the States patrimony through noneappealable judgement and fair compensation” Original text in Spanish, translation provided by the Author. Artículo 2 “La expropiación es una institución de Derecho Público, mediante la cual el Estado actúa en beneficio de una causa de utilidad pública o de interés social, con la finalidad de obtener la transferencia forzosa del derecho de propiedad o algún otro derecho de los particulares, a su patrimonio, mediante sentencia firme y pago oportuno de justa indemnización”

⁶³² Idem

⁶³³ Article 3 from Ley de Expropiación “Goods providing the Republic in general, one or more of its States or territories, one or more municipalities all of those uses and improvements destined for general benefit, and shall be executed by the Republic, the States, the Capital District, municipalities, autonomous institutes, individuals or companies properly authorised” Original text in Spanish, translation provided by the Author. Artículo 3 “Se considerarán como obras de utilidad pública, las que tengan por objeto directo proporcionar a la República en general, a uno o más estados o territorios, a uno o más municipios cualesquiera usos o mejoras que procuren el beneficio común, bien sean ejecutadas por cuenta de la República, de los estados, del Distrito Capital, de los municipios, institutos autónomos, particulares o empresas debidamente autorizadas”

⁶³⁴ Article 60 from Ley de Expropiación, “Expropriation of goods with artistic, historical, architectonical or archeological value will be done according to the present legislation”. Original text in Spanish, translation provided by the Author. Artículo 60 “La expropiación de bienes con valor artístico, histórico, arquitectónico o arqueológico se efectuará de conformidad con lo dispuesto en esta Ley.”

⁶³⁵ Article 115 from Constitución de la República Bolivariana de Venezuela, “Property rights are guaranteed. Everyone has the right to use, enjoyment, possession and disposition of its goods. The law for public utility or public interest will be subject to such contributions, restrictions and obligations imposed on the property. Only for reasons of public utility or social interest by final decision and prompt payment of fair compensation, may the expropriation of any class of goods be declared. Original version in Spanish translation provided by the Author. **Artículo 115.** “Se garantiza el derecho de propiedad. Toda persona tiene derecho al uso, goce, disfrute y disposición de sus bienes. La propiedad estará sometida a las contribuciones, restricciones y obligaciones que establezca la ley con fines de utilidad pública o de interés general. Sólo por causa de utilidad pública o interés social, mediante sentencia firme y pago oportuno de justa indemnización, podrá ser declarada la expropiación de cualquier clase de bienes.”

exclusivity rights and the benefits given by ownership rights.⁶³⁶ In light of Article 546, inventions and patentable subject matters fit within the group of goods susceptible to ownership and property rights. This article specifically mentions products of human ingenuity or derived from a person's talent are of their property and are to be governed by property rights' laws in general, and those especially designed to rule those fields.⁶³⁷ Finally, Article 547CC entails the exception in giving away property rights due public utility or social interest, which shall be carried out through contradicting trial and previous or fair compensation.⁶³⁸

Coming back to the expropriation procedure and its concept, it is important to bring to the spotlight the coercive character embedded in an expropriation. Even though property rights are constitutionally protected, these rights are also limited to the exception of public or social interest. In this respect Venezuela's jurisprudence acknowledged the Governmental need -under certain circumstances - to acquire goods in a coercive manner so as to meet public goals.⁶³⁹ Within the discourse, García de Enterría differentiates between public utility and social interest; arguing that the first one refers to the Administration's need to use particular goods, whereas the second one refers to any interest overlapping the interest of the owner.⁶⁴⁰ In both scenarios, goods are taken over from the owner by the Government to satisfy public interest.

It has been stressed that the severity of expropriating private rights or goods, given that this is a limitation to property rights, and therefore this must be a last resort to satisfy public interest.⁶⁴¹ The same author addresses that expropriation shall not be confused with a sale by means of fair payment; three conditions shall be met before actually expropriating. This is a coercive measure taken to solve a conflict of interest, thereafter, concurrent elements –public utility, final judgment and fair compensation- need to be present prior to public utility or social interest declaration.⁶⁴²

636 Article 545 from Código Civil de Venezuela, Gaceta N° 2.990 Extraordinaria del 26 de Julio de 1982 (hereinafter Código Civil) "Property is the right to use, enjoy and dispose of something in an exclusive manner, with the restrictions and obligations given by Law" Original text in Spanish, translation provided by the Author. Artículo 545 " La propiedad es el derecho de usar, gozar y disponer de una cosa de manera exclusiva, con las restricciones y obligaciones establecidas por la Ley"

637 Article 546 from Código Civil

638 Article 547 from Código Civil

639 Brewer-Carías, Allan., *La Expropiación por Causa de Utilidad Pública o Interés Social: Jurisprudencia, Doctrina Administrativa, Legislación* (Editorial Jurídica Mohigo, Facultad de Derecho, Universidad Central de Venezuela, Caracas, 1966) Colección de Publicaciones del Instituto de Derecho Público, Vol. 2, 1-416 at 27

640 García de Enterría, E., and Fernández, T., *Curso de Derecho Administrativo* (Segunda Edición, Civitas, Madrid, 1988) Vol II, 1-627 at 214

641 Badell Madrid, R., 'Limitaciones al Derecho de Propiedad' in (Artículo publicado en libro homenaje a Gonzalo Pérez Luciani "Temas de Derecho Administrativo", 2002) vol. I <badellgrau.com/?page=render¶ms=id%3D11544487022776&menu_id=m-115133237542#> accessed 31 October 2011

642 Ibid

Satisfying public interest is the main aim. Therewith, a national health emergency would be the sensitive ground to expropriate a pharmaceutical patent or enact a compulsory licence if the Venezuelan IP law foresaw this mechanism.

5.4. Venezuelan Expropriation Procedure and Patent Rights

Without entering into depth about the expropriation procedure, basic steps⁶⁴³ must be highlighted. It is important to assess the expropriation procedure not only because the current IP Law envisages this procedure as a corrective measurement, but also given the current administration's trend in making use or taking over industry and property regardless of the filed as long as its operation is deemed necessary for the government.⁶⁴⁴

This procedure starts with the public utility declaration, which according to Article 13 LEXP is the Assembly or collegiate bodies that are the ones legally enabled to do so.⁶⁴⁵ Generally, the legislation identifies and defines public utility, however the pre-requisite of declaring public utility over a good/right is not completely necessary when these are defined within LEXP and other special laws' context. Scholars have highlighted that a declaration prior expropriation Decree is not completely necessary, provided that both LEXP and Special law –Ley de Propiedad Industrial- already foresee goods and rights object to expropriation without fulfilling the formal legislative declaration.⁶⁴⁶

Continuing with the administrative procedure is the “expropriation decree” per se. This step cannot be reached unless there is a legislative declaration of public utility as provided by Article 5 LEXP. The expropriation decree is also known as the enforcement decree, initiating the administrative procedure by virtue and determination of those expropriation goods.⁶⁴⁷ This formal act brings along three denotable effects, which are expropriation procedure concrete start up, individualisation and specification of the expropriating goods creating the obligation for the owner to transfer property rights to the beneficiary prior to fair compensation.⁶⁴⁸

On the other hand, Article 5 defines the expropriation decree as the declaration stating the execution of works requiring compulsory acquisition of all property or several properties.⁶⁴⁹

⁶⁴³ Article 7 Requisitos de expropiación from Ley de Expropiación

⁶⁴⁴ América Económica, ‘Expropiaciones siguen en la Agenda de Venezuela.

<www.americaeconomia.com/economia-mercados/finanzas/expropiaciones-siguen-en-agenda-de-venezuela> accessed 10 March 2013

⁶⁴⁵ Article 13 from Ley de Expropiación

⁶⁴⁶ Larez Martínez, E., *Manual de Derecho Administrativo* (22th Edition, Venezuela: Exlibris, 2001) 478-621

⁶⁴⁷ Badell Madrid, R., ‘Limitaciones al Derecho de Propiedad’, 2002

⁶⁴⁸ Ibid

⁶⁴⁹ Article 5 Ley de Expropiación “El Decreto de Expropiación consiste en la declaración de que la ejecución de una obra requiere la adquisición forzosa de la totalidad de un bien o varios bienes, o de parte de los mismos. Dicha declaración le corresponderá en el orden nacional, al Presidente de la República, en el orden estatal al Gobernador, y en los municipios a los Alcaldes.

Amicable settlement is also part of the expropriation procedure administrative phase. This settlement deems to negotiate the value of the goods to be expropriated aiming to reach an agreement between the parties. Given the coercive and restrictive character from this procedure, owners have relative freedom to settle the price. If a price is not agreed upon, this will be determined via judicial ruling.⁶⁵⁰

Article 22 LEXP grants thirty -30- continuous days following publication of the Decree for the parties involved to come before the expropriating entity. This publication will be done only one time in the newspaper of major national circulation, and one in the place where the good is located. In this phase, the opportunity is given for the parties to agree upon the value via appraisal commission that shall also be constituted according to legislative provisions.⁶⁵¹ It is not clear whether or not the value provided by the appraisal commission will also be published within the expropriation decree. What is clear is that the owner by accepting a fair compensation amount in this phase relinquishes opposition rights to this offer.⁶⁵² It is important to stress that expropriating goods or determined goods does not involve or imply a direct purchase, since these are completely different procedures.

According to the same provision, owners have five working days following the notification procedure to either accept or reject the fair compensation offered by the expropriating entity. If no agreement is reached over fair compensation, the expropriating party is enabled to reach an agreement over the fair compensation via the judicial system.⁶⁵³ Fair compensation is an appraisal commission that can settle the amount after following strict parameters, which also differentiates this procedure from a simple sale.⁶⁵⁴

There are two ways to conclude an expropriation procedure, either via amicable settlement or pertaining to administrative litigation.⁶⁵⁵ Either way, property valuation by the appraisal commission is necessary. Article 36 LEXP provides obligatory elements to take into consideration when valuating the property.⁶⁵⁶ Furthermore, Articles 38657 and 39658 foresee brief valuation guidelines for

El Decreto de Expropiación requerirá la previa declaratoria de utilidad pública de conformidad con lo establecido en los artículos 13 y 14 de esta Ley”

⁶⁵⁰ Brewer Carías, A., *La Expropiación por Causa de utilidad Pública*, at 69

⁶⁵¹ Article 22, 19 and 20 de Expropiación

⁶⁵² Badell Madrid, R., ‘Limitaciones al Derecho de Propiedad’ at 5.2.3

⁶⁵³ Article 22 Ley de Expropiación

⁶⁵⁴ Badell Madrid ‘Limitaciones al Derecho de Propiedad’ at 4. Características del Instituto Expropiatorio.

⁶⁵⁵ Brewer Carías, A., *La Expropiación por Causa de Utilidad Pública*, at 267

⁶⁵⁶ Article 36 from Ley de Expropiación

⁶⁵⁷ Article 38 from Ley de Expropiación – Valoración de Bienes Muebles (Tangible Assests Valuation) “En el justiprecio de bienes muebles que sean objeto de expropiación, se especificará su clase, calidad, dimensiones, marcas, tipo, modelo, vida útil, estado de conservación y demás características que contribuyan su plena identificación. Los peritos tomarán obligatoriamente en cuenta el valor de adquisición; el valor actualizado, atendiendo al valor de reposición y a la depreciación normalmente aplicable; los precios medios del mercado para bienes muebles similares, y cualesquiera otras circunstancias que influyan en los análisis y cálculos necesarios para realizar el avalúo”

⁶⁵⁸ Article 39 from Ley de Expropiación

both personal property and industries, and goodwill. In cases of taking over goods with artistic, historical, architectural or archaeological value these will be valued accordingly with Articles 60 onwards.⁶⁵⁹

Legislation and different scholars merge at the point that the amicable settlement is exhausted once these 30 days have lapsed, and the acceptance or rejection of it was notified. Once amicable settlement has been exhausted the expropriating entity will require from the competent court to conclude this procedure, therefore transferring the property from the owner to the government. Hence, judicial procedure will only start in three given situations: when the party affected is not willing to reach any amicable settlement; when the property owners are not known; and in cases where taking over the property is of extreme urgency.⁶⁶⁰

Three important phases within this judicial part have been identified. The initial phase starts by: submitting the expropriation petition before the competent court together with the request for those details referred to the property made before the Registrar Office where the property is located; a subpoena is given to all of those who might have an interest in the property; a written answer is given to the mentioned petition, opposition and evidence, relation, reports, rulings and appeals. The Intermediary phase is constituted of the agreement and property value determined by the appraisers designated by the Court. And the final phase is process where the indemnity amount is settled by the Court, effectively transferring the expropriated goods/rights or property by registering the respective the court ruling.⁶⁶¹

Decision INVERSIONES RIFEBA, S.R.L. contra auto del Juzgado Décimo de Primera Instancia en lo Civil, Mercantil y del Tránsito de la Circ. Jud. del Área Metropolitana de Caracas by the Sala Político Administrativa, Tribunal Supremo de Justicia in 2000, also highlighted the precise moment for the conclusion of the expropriation procedure, the one established in LEXP 2002 Article 46 and previously 41.⁶⁶² In this respect the aforementioned provision states that once there is proof of indemnity payment to the expropriated owner, the court hearing the case will request to provide the interested entity with a copy of the decision declaring the expropriation for its formal registration before competent authorities, and thereafter requesting formal and effective property transfer from the expropriated to the requesting entity.⁶⁶³

⁶⁵⁹ Articl 60 from Ley de Expropiación

⁶⁶⁰ Badell Madrid, R., 'Limitaciones al Derecho de Propiedad' at 5.3. El Procedimiento Judicial

⁶⁶¹ Idem Badell Madrid; and *See* Brewer Carías at 74; and, *See* also INVERSIONES RIFEBA, S.R.L. contra auto del Juzgado Décimo de Primera Instancia en lo Civil, Mercantil y del Tránsito de la Circ. Jud. del Área Metropolitana de Caracas, Sala Político Administrativa, Tribunal Supremo de Justicia, República Bolivariana de Venezuela, Expediente Número 12.699 de fecha 5 de Noviembre de 2000 <www.tsj.gov.ve/decisiones/spa/Noviembre/02201-151100-12699%20.htm> accessed 14 September 2013

⁶⁶² Idem INVERSIONES RIFEBA, S.R.L. contra auto del Juzgado Décimo de Primera Instancia en lo Civil, Mercantil y del Tránsito de la Circ. Jud. del Área Metropolitana de Caracas, Sala Político Administrativa, Tribunal Supremo de Justicia, República Bolivariana de Venezuela, Expediente Número 12.699 de fecha 5 de Noviembre de 2000

⁶⁶³ Article 46 from Ley de Expropiación "Once it has been provided proof of indemnity payment, the court hearing the case will order that a copy of its decision declaring the expropriation to be given for its formal registration before the competent office; consequently it will also be ordered that the

Before moving on to the last part of the expropriation procedure, it is important to mention some relevant facts related to those three phases within the expropriation trial highlighted above.

The trial will initiate with a petition made by the expropriating entity to the competent court.⁶⁶⁴ But which is the competent court and how shall the competence be determined? In this respect Article 23 deems competent for hearing the case the Judge in first instance within the Civil Court -Juez en Primera Instancia en lo Civil- at the jurisdiction where the good is located; and for appeals and remedies the competent court in the second instance is the Tribunal Supremo de Justicia -Supreme Court- en Sala Político Administrativa. In case of the República being the one requesting the expropriation of a good, the competent court in the first instance is the Corte Primera en lo Contencioso Administrativo – First Court for Administrative Litigation; and for appeals and remedies it is the Tribunal Supremo en la Sala Político Administrativa – Supreme Court in Political Administrative Chamber.⁶⁶⁵

Once the competent court, depending on the case, acknowledges the case by receiving the petition to expropriate determined good/right or property, this court then, in accord with Article 26, will subpoena owners, holders, leased, creditors and in general everyone having rights over the property intended to be expropriated. In accord with the same article, the court shall subpoena within the three following working days after receiving the petition, and such notification shall be published three times in one month within ten days in between publications in a journal of major national circulation and in one where the good is located.

Following the subpoena, the parties shall present before the court, either in person or represented by proxy, within ten subsequent days to the last publication date. If the interested person or his/her proxy does not come before the Court, this shall designate a public defender to represent the party in the trial.⁶⁶⁶

Another relevant aspect in the first expropriation trial phase is the right to oppose the petition to take over good/right or property. Opposition to the expropriation petition shall be formulated by the party when presenting before the court in the timeframe given in Article 27. The grounds for opposition are established in Article 30 LEXP, that foresees violations to the legal text itself and in cases where expropriating part of the good or property will un-utilise it or damage it totally, hence expropriating part of it is not possible.⁶⁶⁷ The party is to provide the court with proof of ownership or the rights over the good, and proof that the good claimed in the expropriation decree is the same as the one owned by him/her.⁶⁶⁸

competent authority make effective and formal property transfer to the requesting entity” Original text in Spanish, translation provided by the author. **Artículo 46** “Consignada la suma o constancia de haberse realizado el pago al expropiado, el tribunal de la causa ordenará expedir copia de la sentencia que declara la expropiación al que la ha promovido, para su registro en la oficina correspondiente y, además, ordenará a la respectiva autoridad del lugar, haga formal entrega del bien al solicitante.”

⁶⁶⁴ Article 24 from Ley de Expropiación

⁶⁶⁵ Article 23 from Ley de Expropiación

⁶⁶⁶ Article 27 from Ley de Expropiación

⁶⁶⁷ Article 30 from Ley de Expropiación

⁶⁶⁸ Badell Madrid, R., ‘Limited al Derecho de Propiedad’ at 5.3.3.1.d. Contestación y oposición

Right after the final judgment by the court in the first instance, the party can proceed to appeal the ruling and expropriation of the goods in questions before the court in the second instance.⁶⁶⁹ The second phase, as described above, entails agreement and the fair compensation. For the present study's purpose only the appraisal will be made reference to due to the relevance in determining a price or evaluating patent rights.

Fair compensation shall be calculated in a manner to compensate the owner for loosing the property, but not in a way to neither enrich nor deter his patrimony due fair compensation for the expropriated good. In this respect, the purpose of Article 36 and onwards has been quoted before, since those provide the appraisal commission with guidelines and mandatory elements to take into consideration when valuating and appraising the good/right or property. This denotes that these are given for real state, goods and personal property but it is not clear whether or not LEXP's guidelines can also be followed for appraising the aforementioned patent rights.

Finally, the third phase concludes the expropriation trial with the fair compensation payment. Accordingly, there are two moments when the transaction can be achieved, either at the agreement or after the final decision.⁶⁷⁰

The appraisal's commission duty is not limited to estimating the value of the good, but also calculating an indemnity amount to compensate the owner for further damages directly derived from expropriating his/her property or rights.⁶⁷¹ Article 37, 39 and 41 LEXP refer to cases where indemnity for damages is applicable. For all of the cases an indemnity is due for further damages foreseen; either permanent damage derived from the property loss or due to diminishing rights with the expropriation.⁶⁷²

In the light of Article 40's indemnity in cases of permanent loss caused to the right holder, it could be argued that patent right holders could get both a fair compensation and also indemnity due having their right taken over. But it still remains to determine whether or not valuation guidelines provided by LEXP are sufficient to appraise patent or intellectual property rights in general.

As denoted above, the expropriation procedure brings to the spotlight many questions that will be addressed within the summary at the end of this chapter.

⁶⁶⁹ See idem Badell Madrid, and Article 33 "The timeframe to appeal thos decision from the Court in First instance is of five (5) days". Original text in Spanish, translation provided by the author Artículo 33 " El Término para apelar de las decisions de Primera instancia srá de cinco (5) días"

⁶⁷⁰ Idem.

⁶⁷¹ Lares Martínez, E., 'Los Proceimientos de Expropiación' in *Manual de Derecho Administrativo*, (12º Edición Actualizada a la Constitución de 1999, Facultad de Ciencias Jurídicas y Políticas de la Universidad Central de Venezuela:Caracas, 2001) 9-742, at 611

⁶⁷² See further Article 40 from Ley de Expropiación "Habrá lugar a la indmenización cuando a los propietarios ... sufran un daño permanente que se derive de la pérdida o de la disminución de sus derechos." Modification of the article and translation provided by the author, "In cases of ... permanent damage cause to the owners or when their rights have been diminished an indemnity will proceed to compensate for these"

5.4.1. Grounds for Patent Extinction

As mentioned before, the Venezuelan IP law foresees certain cases when patent rights may be recalled or extinguished, specifically in Article 17 a series of scenarios justify the extinction of the right. For instance, Patents are left without effects in cases of nullity, when voided, non-payment of annual fees, expiration of patent protection term and by express resignation of patent rights by the inventor or right holders.

The first case for patent nullity is a due court ruling in favour of a better right.⁶⁷³ Another case for nullity is due to the fact that patents do not meet essential patentability requirements, hence giving Courts enough grounds to rule against the right initially granted.⁶⁷⁴ Article 17(a) provision is also complemented by Articles 63 and 66, where both the period for opposing patent claims and the right to present a petition to void patent rights before competent courts are settled.

When reading these articles in conjunction, a better right could not only be the inventor's genuine right over the good but also public interest. However, the fact that the legislation foresees protection for third parties' better rights does not seem to be either limited to only those cases stated above or clear to what extent third party rights could be deterred. In this respect, Article 66 from the IP Law from 1955 envisages a period of two years counted from the date the certificate was issued. This is perceived as extreme protection to third parties and also constituting a limit in itself for patent holders' legitimacy to exploit their patent rights.

Patent rights should meet a working requirement, which if breached will provide grounds to revoke the rights since they will be failing to comply with the non-working clause within the law.⁶⁷⁵

Other cases qualifying for patent nullity as stated in Article 17 are those provided in Articles 12 and 21, where the law acknowledges the original inventor's rights. Therefore, any patent claim for improvements or introduction granted to another person shall be revoked or voided in the original inventor's favour.⁶⁷⁶ And the

⁶⁷³ Article 17 from Ley de Propiedad Industrial "Patents are left without effect: a. nullity due court ruling by compente authorities when these are considered to go against the best right of third parties; d. nullity in light of articles 12 and 21 from the same law"

⁶⁷⁴ Benito Sansó, at 23

⁶⁷⁵ Article 17 (c) from Ley de Propiedad Industrial "When the patent holder let pass two (2) years from the grant date, without exploitation in Venezuela, or when the exploitation was interrupted for an equal period of time, expect in cases of force majour properly proven before the Patent Office, patents will be left without effects" Original text in Spanish, translation provided by the author. "Cuando el titular de un patente haya dejado transcurrir dos (2) años, contados a partir desde la fecha de su expedición, sin explotar en Venezuela el invento que las motivo, o cuando se interrumpa la explotación por un tiempo igual, salvo caso fortuito o fuerza mayor, debidamente comprobado ante la Oficina de Registro de la Propiedad Industrial;" Aslo see further Benito Sansó "Las Patentes de Invección" at 24

⁶⁷⁶ Article 12 from Ley de Propiedad Industrial

Ministro de Fomento shall revoke patent rights granted in contravention with the law, after proper justification from the Registrar.⁶⁷⁷

Venezuelan IP Law envisages local working requirement as grounds to void patent rights, as stated above. If a patent has been left without exploitation or work for a period equivalent to 2 years, unless force majeure can be proven, the Government is entitled not only to take back the patent rights granted but also make the information part of the public domain.⁶⁷⁸

Loosing patent rights due to unpaid annual fees to SAPI is perhaps the only case within the legislation when these rights can be re-enacted or rehabilitated. Article 19 entails the possibility of reinstating patent rights if the patent holder petitions before the Registrar, after payment of annual fees and the fine given by law.⁶⁷⁹ On the one hand, the article envisages suspension of patent rights, and on the other opens the possibility to lose permanently patent rights if neither the fine nor fees are paid within the period of time given by law.

Patent rights are extinguished in two cases, either by expiration of patent term protection or by express resignation on the inventor's behalf. Article 17 letters e)⁶⁸⁰ and f)⁶⁸¹ foresee in a clear cut manner this extinction of rights, thereafter becoming part of the public domain in light of Article 20.

⁶⁷⁷ Article 21 from Ley de Propiedad Industrial "At all times the Ministro de Fomento, prior Registrar's report, shall revoke patent rights over inventions, improvements, models or industrial drawings in a resolution explaining the reasons contravening the law. Interested parties shall appeal before Federal Court within three (3) months from the date the resolution was published in Gaceta Oficial" Original text in Spanish, translation provided by the author. Artículo 21 "En todo tiempo podrá el Ministro de Fomento, previo informe del Registrador de la propiedad Industrial, anular, en Resolución razonada el registro de los inventos, mejoras, o modelos o diseños industriales, obtenidos en contravención a esta Ley. La parte interesada podrá interponer recurso de apelación para ante la Corte Federal dentro del lapso de tres (3) meses, contados desde la fecha en que se publique la resolución en la Gaceta Oficial."

⁶⁷⁸ See Article 17(c) from Ley de Propiedad Industrial

⁶⁷⁹ Article 19 from Ley de Propiedad Industrial "Patent rights left without effect due to unpaid annual fees, in light of Article 17 (d), can be reinstated only one time if the patent holder petitions its reinstatement before SAPI within a period of three (3) months from the expiration date to pay annual fees, and after payment of the debt plus double the amount. The Registrar will provide the patent holder with a certificate reinstating patent rights, and this decision will be published at the Boletín de la Propiedad Industrial" Original text in Spanish, translation provided by the author.

Artículo 19 "La patente que haya quedado sin efecto por falta de pago de una anualidad conforme a la letra d) del Artículo 17, podrá ser rehabilitada por una sola vez, si su titular lo solicita ante la Oficina de Registro de la Propiedad Industrial, dentro de los tres (3) meses siguientes al vencimiento de plazo establecido para el pago de la anualidad, previo pago al Fisco de la cantidad adeudada más el doble de la misma. El Registrador otorgará al interesado constancia de la rehabilitación y hará la correspondiente publicación en el Boletín de la Propiedad Industrial"

⁶⁸⁰ Article 17 from Ley de Propiedad Industrial "Patents will be left without effects (e) when the time of protection expires" Original text in Spanish, translation provided by the author. Artículo 17 "Las patentes quedan sin efectos: (e) Por el vencimiento del término; y"

⁶⁸¹ Article 17 from Ley de Propiedad Industrial, "Patents will be left without effects (f) by express resignation on the inventor's behalf" Original text in Spanish translation provided by the author.

Artículo 17 "Las patentes quedan sin efectos: (f) Por renuncia expresa del inventor"

Scholars have also suggested as the first case for patent exhaustion, the limitation in time of patent rights or in other words once the patent expires the rights are exhausted.⁶⁸²

5.4.2. Grant Procedure and Registration

The grant procedure as foreseen in Chapter IX from the 1955 IP Law regulates everything related to the application, including cases that request patent nullity, and void by third parties. Firstly, it can be denoted that patent protection can only be applied for by the “real inventor” or those looking to either introduce and invention or improvements,⁶⁸³ in accord with Article 58.⁶⁸⁴ And secondly, Article 59 begins summarising the requirements to present and to be annexed within the patent claim. Among these, special attention will be later on given to the patent disclosure.

Besides presenting the patent claim form, a simple copy of the same form shall be presented before SAPI, in which, both basic inventors information such as name, address and nationality shall be given, together with a statement certifying that the inventor is the “real inventor”. Some other information is also required, but thus far the most important requirements deem the novelty of the invention, which seems to rely on the inventor.⁶⁸⁵ On the one hand, global novelty is required but on the other, novelty within the Venezuelan territory seems to be sufficient. However, this provision seems to contradict the cause for patent rejection based on public knowledge either in Venezuela or abroad provided in Article 15(9°).

At a first glance, providing the Registrar with the number, date and place where this was granted, does not seem to be enough. The inventor shall also hand in legalised Spanish translation of the foreign patent certificate. There with proving, the patent is still valid and that protection can be granted for the time before this lapses in the foreign country.⁶⁸⁶ On a second glance, only providing the registrar

⁶⁸² Astudillo Gómez, F., *La Protección Legal de las Invenciones: Especial referencia a la biotecnología* (Colección Ciencias Sociales, Serie Jurídica, 1ra Edición, Universidad de los Andes, Mérida – 1995) 1-412, at 121

⁶⁸³ Article 14 from Ley de Propiedad Industrial

⁶⁸⁴ Article 58 Ley de Propiedad Industrial, “Patents for inventions and discoveries within parts 1, 2, 3, 4, 5, 6, 7 and 8 from Article 14 can only be claimed by the inventor or the one looking to either introduce an improvement or a product envisaged in part 9 from the same article 14”. Original text in Spanish, translation provided by the author. **Artículo 58** “Podrán solicitar patentes los inventores o descubridores de los objetos a que se refieren los numerales 1, 2, 3, 4, 5, 6, 7 y 8, del Artículo 14, y los introductores de las invenciones o mejoras a que se refiere el ordinal 9° del mismo artículo citado”

⁶⁸⁵ Article 59, 1° (d) Ley de Propiedad Industrial, “That the object of the invention has never been used in Venezuela” Original text in Spanish, translation provided by the author. **Artículo 59 (d)** “Que el objeto de la patente no ha sido utilizado en ningún caso en Venezuela;”

⁶⁸⁶ Article 59, 1°(g) Ley de Propiedad Industrial, “Number, date and origin of the foreign patent or source of information necessary when this are not known, *in cases of patents for introducing an invention*” **2° (d)** “Patent certificate in a certified copy, legalised and translated into Spanish, in case of *patent claim for inventions, discoveries, improvements or models or industrial drawings already patented abroad;*” and **3°** Proof that the foreign patent is still valid and how long before the expiration date remains in the country of origin, *for those cases when the patent claim verses*

with the information source in case of not knowing necessary details could⁶⁸⁷ pose a problem in term of legal certainty. Perhaps this is the reason the law gives a period of two years to claim patent nullity for these kinds of patents.

In light of those quoted articles within the footnotes, two questions arise from the fact that further or complete proof seems to be only necessary in cases of patents already granted abroad for inventions, discoveries, improvements, models or industrial drawings, but that is not deemed applicable for patents for introducing an invention. By this point the legislation once more makes clear the distinction between patent types and burden of proof. Hence, in light of these provisions further proof is to be provided only in those aforementioned cases; and given that the Registrars function is to study the files, this obligation might suffice for the verification of foreign information that might not even be in SAPI's official language.

The patent disclosure is foreseen as an invention's descriptive memory, that shall clearly describe the patentable subject matter in a specific, complete and exact way as possible, particularly to manufacture, produce and for the procedure of manufacture or composition.⁶⁸⁸ Just to mention a few cases relevant for the pharmaceutical industry.

Moreover, the Venezuelan grant procedure is without examination unless there is opposition. The Administration excludes itself from examining the invention's novelty, utility and industrial applicability unless a third party opposes the patent claim. In which case, the Administration will examine the patent claim but only with regard to the opposition.⁶⁸⁹ Some scholars have suggested that Venezuela's grant procedure as stated in the IP Law from 1955 is actually a system of attenuated previous examination with call to opposition from third parties.⁶⁹⁰

over inventions, discoveries, improvements, models or industrial drawings already patented abroad." Original text in Spanish, translation and italics provided by the author. **Artículo 59, 1º(g)** "El número, fecha y origen de la patente extranjera o la fuente de información necesaria en caso de que ignore esos datos, cuando se trate de patentes de introducción." **2º (d)** "Copia certificada, legalizada y traducida al castellano de las letras patentes del país de origen, en caso de solicitud de patente para una invención, descubrimientos, mejore o modelos o dibujos industriales, ya patentados en otro país;" and **3º** "Comprobar que la patente extranjera está vigente y el tiempo que falte para vencerse en el país de origen, en caso de solicitud de patente para una invención, descubrimiento, mejora, modelo o dibujo industrial, ya patentados en otro país."

⁶⁸⁷ Idem Article 59 1º(g)

⁶⁸⁸ Article 59, 2º (a) Ley de Propiedad Industrial, "two descriptive memory copies in Spanish, describing in a clear manner the object seeking patent protection, with complete and exact specifications from both the operating and methodology to build, make or combine the corresponding machinery, manufacture, material composition, procedure, improvement o model or industrial drawings;" Original text in Spanish, translation and remarks by the author. **Artículo 50, 2º (a)** "Una memoria por duplicado y en idioma castellano, en la que describa con la mayor claridad, el objeto industrial sobre la cual ha de recaer la patente, con especificación completa y exacta de la operación y método de construir, hacer o combinar la correspondiente máquina, manufactura, composición de material, procedimiento, mejora o modelo o dibujo industriales;"

⁶⁸⁹ Benito Sansó 'Las Patentes de Invención' at 31

⁶⁹⁰ Uzcátegui Urdaneta, M., 'El Orden Jurídico Industrial' in *Invención y Patentes de Invención en el Derecho Venezolano* at 95

The burden of proof falls with the inventor and/or successors in a subjective manner. This happens, as highlighted above, by requiring the part to provide proof of being the “real inventor.” Also it denotes how SAPI limits to verify over documentation provided without further inquires, unless -as mentioned a few times before- this right were to be contested by third parties.

Other scholars address the grant procedure in the light of the national law as a declarative act on behalf of the administration, since this one based on a *iuris tantum* presumption, only recognises or verifies the existing rights from the moment the invention was created. This enables the inventor to claim patent rights in his/her name, formulate opposition on the basis of his/her better right and request nullity action against patents granted to third parties.⁶⁹¹

To a certain extent, part of the aforementioned statement contradicts part of the doctrine. Despite being a declarative act on behalf of the administration the burden of proof relies on the inventor, since this is the one proving who he is and the administrations takes his word for it, as it does not thoroughly verify the veracity of these claims.

The grant procedure involves publication of the decisions. This publication should be done via the newspapers of major circulation in the country and for three times. Once the three publications are fulfilled, then it will be published in the *Boletín de Propiedad Industrial- Industrial Property Official Journal*.⁶⁹² The period to formulate opposition will begin on the same date as the decision publication within the official industrial property journal. The parties will initially have 60 days to oppose the patent claim, and then as mentioned before up to two years for requesting to null and void patent rights based on misappropriation or prior inventor.

Recognising who the prior inventor or real inventor is, in case of a nullity trial, could be complicated especially in cases when the inventor has either transferred or forgone his rights to a company that is the one presenting the patent claim before SAPI. Even though the real inventor is not the company, by the Law foreseeing the possibility for an inventor to relinquish his rights to a company, this one is legally entitled to present opposition instead of the inventor.⁶⁹³

If a patent claim fails to comply with those requirements settled in Articles 49 and 59, the registrar will return the patent claim to the interested party. Granting a 30-day period to solve or comply with missing requirements, this period can be extended for up to three months if the Registrar, after petition on the interested party's behalf, considers adequate such an extension.⁶⁹⁴

⁶⁹¹ Astudillo Gómez, F., ‘La Protección legal de las invenciones: Especial referencia a la biotecnología’ (Colección: Ciencias Sociales, Serie: Jurídica, 1ra Edición, Universidad de los Andes, Mérida-1995) 1-412, at 88-89

⁶⁹² Article 60 Ley de Propiedad Industrial

⁶⁹³ Uzcátegui Urdaneta ‘Invención y Patentes de Invención’ at 97

⁶⁹⁴ Article 61 Ley de Propiedad Industrial, “The Registrar shall return patent claims when interested parties are not in compliance with Articles 49 and 59 from this Law, a rationale for such a rejection shall also be provided. Returning a patent claim accordingly with this Law does not extinguish priority rights if the patent claim fulfilling the requirements is presented before a period of thirty (30) days from the return date of the claim.... Is the Registrar's faculty to extend the

Following with the legislative analysis, Article 62 points out the cases for denying a patent claim. Basically, patents falling out of Article's 14 and within Article's 15 scopes will be denied by the Registrar.⁶⁹⁵As mentioned before, right after the publication and for a period of 60 days, all interested parties may oppose a patent claim but they are not restricted to present opposition to this period. Article 63 read in conjunction with Article 60, gives 19 days in total to oppose a patent, and then up to two years as highlighted above for specific cases. In light of Article 63, a person may oppose in three cases: first, because he/she considers the invention to be non-patentable and not falling within Article's 15 scope; secondly, because he/she was granted a patent abroad;⁶⁹⁶ and thirdly, because the one opposing the patent claim considers to have a better right or to have been the real inventor to the one presenting the claim.⁶⁹⁷

Once someone has presented opposition, the patent claimant will be informed via Boletín de la Propiedad Industrial. This has a period of 15 working days from the publication date to come before SAPI and learn about the opposition made to the patent claim. Once these 15 working days have expired, another period of 15 working days will start running for the claimant to respond to the opposition's reasoning against it.⁶⁹⁸

compliance period for up to three (3) months, previous petition on the interested party's behalf, when the Registrar consideres suitable on a case by case basis" Original text in Spanish, translation and modification by the author. **Artículo 61** "Si el solicitante no cumpliera con los requisitos establecidos en los artículos 49 y 59 de esta Ley, el Registrador devolverá al interesado la solicitud que hubiere presentado, con exposición de las razones en que funde la devolución. La devolución, de conformidad con este artículo, no extingue el derecho de prioridad de la presentación, si en el plazo de treinta (30) días contados desde la fecha de la devolución, fuere consignada nuevamente la solicitud con las correcciones del caso ... El registrador queda facultado para prorrogar este plazo hasta por el término de tres meses, previa solicitud del interesado, cuando a juicio de aquél la naturaleza del asunto así lo requiera."

⁶⁹⁵ Article 62 Ley de Propiedad Industrial, "When a patent claim is not within Article 14 but within Article 15's scope it will be denied by the Registrar, whom shall provide a resolution reasoning the basis for denying the patent claim" Original text in Spanish, translation by the author. **Article 62** "Cuando la solicitud no se encuentre comprendida en los casos del artículo 14 o se encuentre incurso en las prohibiciones contempladas en el artículo 15 de la esta Ley se negará su registro mediante resolución del Registrador en la cual indicará la causa de la negativa"

⁶⁹⁶ See Article 11 Ley de Propiedad Industrial

⁶⁹⁷ Article 63 Ley de Propiedad Industrial, "During the publication period and sixty days after this one expires, any person shall object and oppose the patent grant: **1º** to consider patent subject matter to fall outside of Article 14's and within Article 15's scopes of patentability; **2º** Because the patentable subject matter falls within the scope of Article 11; and, **3º** Because he/she is the real inventor or believes to have a better right that the one who presented the patent claim" Original text in Spanish, translation provided by the author. **Artículo 63** "Durante el lapso de publicaciones y sesenta días después de expirado éste, cualquiera persona podrá objetar la solicitud y oponerse a la concesión de la patente: **1º** Por considerar que el objeto de la patente no se halla comprendido en los casos contemplados en el artículo 14 de esta Ley o que está incurso en las prohibiciones establecidas en el artículo 15 de la misma; **2º** Por encontrarse en el caso previsto en el artículo 11 de la Ley; y **3º** Por considerarse el opositor autor del invento o con mayor derecho que el solicitante."

⁶⁹⁸ See Article 63, second paragraph Ley de Propiedad Industrial, "Opposition will be notified to the patent claimant via notice within Boletín de la Propiedad Industrial, for him to come before SAPI to learn about the opposition made to the patent claim within fifteen working days from the publication date. Once these expires a new period of fifteen working days will start running for the claimant to response against the opposition made." Original text in Spanish, translation provided by

In light of Articles 63 and 64, the Registrar is the one who solves the opposition, especially when analysing whether or not the invention falls outside of the scope of a protection case, taking into consideration both proof and facts provided by the parties and the ones brought to his own attention.⁶⁹⁹ In this case, and in accord with Article 64, the Registrar has the possibility to consult technical official bodies and/or experts in the field to solve and determine whether or not the invention claiming patent protection really falls outside of the scope of protection as formulated within opposition procedure.⁷⁰⁰ To solve oppositions presented regarding better right or infringement of priority rights, the file needs to be passed on to the Civil Court in the First Instance who will decide whether or not the patent shall be granted or voided.⁷⁰¹

Besides express mention of the Registrar's limitation to solve opposition for those aforementioned cases, there are no further provisions on this procedure. Thereafter, those principles embedded in the Venezuelan Civil Procedure are applicable to determine available judicial remedies when pursuing a solution. In this respect, Article 16 Código de Procedimiento Civil – Civil Procedure Code, herein CPC- highlights that civil action can be pursued as long as the interest justifies it; and the interest can be limited to determine whether or not certain rights or juridical relations exist.⁷⁰²

Therewith, civil procedure entitles protection of the patent holder's moral right over the invention as follows: it recognises him/her as the inventor; protects his/her right to exclude others from freely using the invention by pursuing civil actions addressed to void and extinguish patent rights granted wrongfully; and allows the inventor to pursue actions strictly linked to the exclusivity of the right, or in other words the exclusive right entitles the patent holder to seek remedies for the defence of this right.⁷⁰³ Civil sanctions include, monetary compensation for patrimonial damages caused to the patent holder,⁷⁰⁴ moral right indemnity⁷⁰⁵

the author. **Artículo 63, parágrafo Segundo** “La oposición se notificará al solicitante por medio de aviso en el Boletín de la Propiedad Industrial, para que comparezca a informarse de auélla en el plazo de quince días hábiles a contra a partir de la publicación. Vencido dicho plazo comenzará a correr un plazo de quince días hábiles para que el solicitante aduzca lo que estime conveniente a sus derechos.”

⁶⁹⁹ Benito Sansó “Las Patentes de Invención”, at 31

⁷⁰⁰ See Uzcátegui Urdaneta “Sistemas de Concesión” in Patentes y Patentes de Invención en el Derecho Venezolano, at 118; and see Article 64 Ley de Propiedad Industrial

⁷⁰¹ Article 63 third paragraph Ley de Propiedad Industrial, “... For the second and third case, the Registrar will pass on the file to Civil Court in First Instance to solve the opposition with the proves presented before him according to ordinary trial proceedings, while at the same time suspending the administrative procedure to grant the patent until the Court reaches a decision and the interested party re starts the grant procedure” Original text in Spanish, translation provided by the author. **Artículo 63, tercer párrafo** “... en el Segundo y tercer caso, el Registrador pasará el expediente al Tribunal de Primera Instancia en lo Civil para que éste resuelva la oposición con las pruebas que ante él se presentan según los trámites del juicio ordinario, y suspenderá el procedimiento administrativo de consecución de la patente hasta que el Tribunal decida y la parte interesada gestione nuevamente el asunto.”

⁷⁰² Article 16 Código de Procedimiento Civil, Gaceta Oficial N° 4. 209Extraordinaria de fecha 18 de Septiembre de 1990 (hereinafter Código de Procedimiento Civil)

⁷⁰³ Benito Sansó “Las Patentes de Invención” at 32

⁷⁰⁴ Article 1185 from Código Civil

⁷⁰⁵ Article 1196 from Código Civil

and seizure and destruction⁷⁰⁶ of those products infringing the patent holder's rights.

Article 66 LPI reinforce the possibility of a civil trial for up to two years if there was no opposition during the time foreseen to do that and if patent rights were granted in detriment of third parties rights, as mentioned several times before. Once the opposition has passed or met all patentability requirements, a patent certificate will be granted and issued in accord with Article 68. This certificate shall indicate basic information, most importantly expiration date. Registration procedure is dealt with in Chapter XI, Article 92 to 96 where fees owed to SAPI are established. All of these need to be read according to newer provisions given the change in fiscal unit value.

Besides having the possibility to solve oppositions via civil courts, the 1955 IP Law envisages criminal remedies as well. Chapter XII begins with Article 97 where reference is made to the penal code's typified crimes against intellectual property. This law also describes and typifies infringements and penalties for each of them.

For patent infringements, according to this IP Law, an infringer faces jail from one to twelve months. Expressly manufacture, reproduction, transferring or using patented inventions without the patent holders consent will be considered as an infringement punishable by law. Hence, introducing criminal sanction possibilities as corrective measures.

Article 104 of IP Law brings to the spotlight the fact that criminal actions can only start by petition on the aggravated party's behalf. Thus, a criminal proceeding will rule over the matter, not only establishing the sum due compensation for damages but also seizing and destroying illegal goods together with everything used to manufacture or to produce them.⁷⁰⁷

Scholars have highlighted the importance in determining if the illegal patent appropriation by making use of the invention without authorisation was done in a manner so as to commercially benefit from it or not. Without having determined illegal commercial exploitation, typifying the crime seems difficult; hence, no criminal sanction could be applicable. Criminal intent needs to be evident to determine the crime. In other words, the will to misappropriate the patented good, and have the knowledge about the existence of patent protection are needed. This knowledge is assumable by the fact that this protection is of public knowledge once it has been published in Boletín de Propiedad Industrial. Thus, criminal intent is embedded within the action of the infringer.⁷⁰⁸

⁷⁰⁶ Article 1268 from Código Civil

⁷⁰⁷Article 105 from Ley de Propiedad Industrial "In every crime ruling establishing intellectual property infringements will contain an order to seize and destroy illegal goods and instruments used to produce or manufacture them." Original text in Spanish, translation provided by the author.

Artículo 105 "En toda sentencia condenatoria por delito contra la Propiedad Industrial se ordenará la destrucción de los instrumentos que hayan servido o estuvieren preparados para la comisión del delito, así como los objetos que provengan de los mismos." See also, Benito Sansó "Las Patentes de Invención en Venezuela" at 34-35

⁷⁰⁸ Idem Benito Sansó.

Accordingly, patent infringers will either face criminal penalties, or civil sanctions shall also be applicable, to compensate for patent holders' losses. Chapter XIV contains transitional provisions addressed to solve questions emerging from patent claims caught in the pipeline; in other words, patent applications not published or in first and second publication at the time this 1955 IP Law came in force.

Articles 108 to 110 established that these patents will be decided on the basis of this Law despite the fact that claimants might have had formulated their claims having a wider or completely different regime in force at that moment. By 1955, this legislation might have had benefited claimants, but if followed for claims structured under the umbrella of Andean Community IP Regime the current framework might prove challenging.

5.5. Intellectual Property Regime in Venezuela Prior to the Withdrawal from the Andean Community

Within the National legislation hierarchy there is an important aspect to be taken into consideration. That is, the legal framework given by the Andean Community (hereinafter ACN) for intellectual property rights and related rights. Before moving on to describe the legislation and the challenges brought to Venezuela due to its membership of the Andean Pact as it is also known, perhaps it is better to start analysing the implications, nature and functions of this organisation.

The Andean Pact, as originally named, is a sub regional integration organisation created in 1969 and its aim was to harmonise policies, define a common external tariff, liberalise integration trade, regulate foreign direct investment and organise production across member Andean countries.⁷⁰⁹ Five countries came together under the integration organisation aiming to improve its people's living conditions.

Facing almost a full failure, by 1985 the Andean pact needed to revise its policies and readdress strategies to consolidate later on in 1987 as a trade area. The Trujillo Protocol of 1996 reshaped the organisation into what it is known today as the Andean Community of Nations. This time the emphasis was on open regionalism, establishing the Andean Free Trade Zone and the Andean Customs Union. During the 90s the organisation's governance changed, shifting from merely trade-oriented policies into a political, social and economic integration agreement aiming to achieve similar goals as those from the European Union, but on a smaller scale. The country members and initial founders were Bolivia, Colombia, Chile, Ecuador and Peru, with Venezuela becoming a member state in 1973.⁷¹⁰

In accord with the Cartagena Agreement, each country had to sign the agreement in full, with no reservations allowed and once deposited in each of the member

⁷⁰⁹ Creamer, G., 'Andean Community' *Andean Community Journal* at 61

⁷¹⁰ Andean Community, Who are we, brief history, <www.comunidadandina.org>

states for ratification then it was understood that the Agreement was in force in that country.⁷¹¹

5.5.1. Bodies, Institutions and Jurisdiction

Another interesting feature of this sub-regional integration organization is the 14 bodies and institutions constituting it, given that it also entails a division of powers.

The Andean legal order is structured in six bodies and eight institutions. The executive, legislative and judicial bodies comprise of the following: the Andean Council of Presidents, Andean Council of Foreign Affairs, Andean Community Commission, Andean Community Secretariat, Andean Community Court of Justice and the Andean Parliament. The financial, integration and educative institutions are as follows: the Andean Development Corporation, Latin American Reserve Fund, Andean Business Advisory Council, Consultative Council of the Indigenous Peoples – it is a consultative body-, Andean Health Body, Simón Rodríguez Convention and Simón Bolívar's Andean University.

Each of these has delimited functions and competences, but the Andean Community Commission and the Andean Community Court of Justice are the most important bodies within the organisation. The Andean Community Commission is the main policy making body and the Andean Community Court of Justice is the judicial body, which has territorial jurisdiction in the four countries as well as being the only body that actually can interpret community law and settle disputes among member states or derived from community law.⁷¹²

5.5.2. Principles of the Andean Community

The Andean Community's characteristic principles are to be found within the Treaty Creating the Andean Community Court of Justice created in Cartagena on 28 May 1979. Venezuela ratified the agreement in 1983, thereafter coming into force 2 January 1984.⁷¹³ A later Treaty amendment in 1996 named the Protocol of Modification of the Treaty Establishing the Court of Justice of the Andean Community brought significant changes to the principles, since the member states now agree on giving direct implementation to Court Decisions and also broader jurisdiction.⁷¹⁴

⁷¹¹ Cartagena Agreement final provision

⁷¹² Andean Community, Andean Court of justice, *comunidad andina.org*.

⁷¹³ SÁCHICA, L., *Derecho Comunitario Andino*, (Segunda Edición, 1990) at 100

⁷¹⁴ Id ut Supra SÁCHICA, at 98. Previous the amendment Community Law was considered to be secondary law in each national framework, given that decision and resolutions came into force when each member found suitable instead of when it was required; there was no uniformity in interpreting community law neither real possibilities to harmonise the system

With the amendment to the first treaty, the rules became somewhat clearer having as principles direct implementation,⁷¹⁵ preferred implementation⁷¹⁶ and immediate application.

Direct implementation and direct effect principles, in the words of the Court of Justice, are correlated. Thus, community law that has direct implementation within member Countries has direct effects on its nationals. This means, that once rights and duties are created they enable nationals to claim and feel protected by them.⁷¹⁷ As a concluding remark, in a different procedure where the above was quoted by the Court, it is emphasised that those legal norms becoming part of internal legislation are directly applicable with direct effects, given that from the moment those are published in the Official Gazette means they are binding and immediately implemented by Country Members.⁷¹⁸ Moreover, in 1999 the Court ratified its position regarding the direct implementation principle where it is suggested that the sole idea of discussing or analysing community law within the context of each national legislation denies the possibility of having community law at all.⁷¹⁹ Hence, is it inadmissible that Country Members use an internal legal framework as an excuse for breaching and not implementing Community Law.⁷²⁰

Preferred implementation is to be found in the Treaty's Article 4° when it is stated that, "Member Countries are under the obligation to take such measures as may be necessary to ensure compliance with the provisions comprising the legal system of the Andean Community. They further agree to refrain from adopting or employing any such measure as may be contrary to those provisions or that may in any way restrict their application"⁷²¹ According to Fabián Novak Talavera, this means that a Member Country cannot base its non-compliance with community law on having a contrary national framework, because the Member's duty is to

⁷¹⁵ Article 3 from Treaty creating the Court of Justice of the Cartagena Agreement (hereinafter Andean Court of Justice Treaty) "Decisions of the Andean Council of Foreign Ministers or of the Commission and Resolutions of the General Secretariat shall be directly applicable in Member Countries as of the date they are published in the Official Gazette of the Agreement, unless they indicate a later date."

<www.comunidadandina.org/ingles/normativa/ande_trie2.htm> accessed 14 September 2013

⁷¹⁶ Article 4 from the Andean Court of Justice Treaty, "Member Countries are under the obligation to take such measures as may be necessary to ensure compliance with the provisions comprising the legal system of the Andean Community. They further agree to refrain from adopting or employing any such measure as may be contrary to those provisions or that may in any way restrict their application"

⁷¹⁷ Tribunal De Justicia de la Comunidad Andina, proceso N° 03-AI-96 del 24 de Marzo de 1997<intranet.comunidadandina.org/Documentos/Gacetitas/Gace261.pdf> accessed 14 September 2013

⁷¹⁸ Tribunal De Justicia De la Comunidad Andina, Proceso N° 07-AI-99 del 12 de Noviembre de 1999. Original text in Spanish "En conclusión, las normas que conforman el ordenamiento jurídico andino, cualquiera que sea su forma (Tratados, Protocolos, Acuerdos, Convenios o Resoluciones) son, por regla, de efecto y aplicación directa en todos los Países Miembros desde su publicación en la Gaceta Oficial del Acuerdo de Cartagena, lo que significa que son de obligatorio e inmediato cumplimiento por los Países Miembros, los órganos del Acuerdo y los particulares."

⁷¹⁹ Id ut Supra, Proceso N° 07-AI-99 quoting Proceso N° 03-AI-96, at 10-11

⁷²⁰ Novak Talavera, F., 'La Comunidd Andina y Su Ordenamiento Jurídico' in *Derecho Comunitario Andino* (1^{ra} Edición, Pontificia Universidad Católica del Perú:Lima, 2003) 57-100, at 72

⁷²¹ Id ut Supra Article 4° from Andean Court of Justice Treaty

adapt the internal legislation as to allow community law's governing principles to function as established within the agreement.⁷²²

Immediate application principle within the context of the Andean Community refers to the instant entry into force of those resolutions creating rights and duties, and rulings from the Court, by mere publication in the Official Gazette from the Cartagena Agreement.⁷²³

5.5.3. Challenges and Implications for Venezuela as an Andean Community Member

The aforementioned principles brings to the spotlight the supra-national character of the Andean Community, which has also been contested by Venezuela, as will be described below. Given the nature of the principles described above, it is only natural to assume that the Andean Community is a supra national organisation. This can also be inferred due to the transfer and giving up - to a certain extent - of some State competences to the Andean Judicial Body. Furthermore, the concept of sovereignty had to evolve at least in theory as to allow the survival of these sub-regional integration organisations.⁷²⁴

To assess the impact and inconsistencies when joining the Andean Community, the Venezuelan Constitution from 1961 needs to be taken into consideration since this was the version in force at that time. In this respect, Article 128⁷²⁵ stipulated that before any international treaty could become part of the national legal framework, it had to be either sanctioned by the Parliament or approved via Presidential Decree, depending on whether or not this dealt with areas reserved to the Constitution. In other words, if the foreign framework modifies the national legislation then Parliamentary approval followed by its publication within the Official Journal was required, as happened with the Cartagena Agreement. This Agreement was approved and published in Gaceta Oficial No: 1620 01-11-1973. Moreover, the approbatory law within its only paragraph stated precisely this:

Those decisions made by the Cartagena Agreement Commission that modify Venezuela's legislation, or deal with areas assigned to the legislative power, shall be approved by law sanctioned by the Venezuelan Congress⁷²⁶

⁷²² Novak Talavera., F., 'La Comunidd Andina y Su Ordenamiento Jurídico', at pp 76

⁷²³ Idem Novak Talavera, F., at 78

⁷²⁴ Pérez Navarro, L., 'Los Principio Básicos del Derecho Comunitario en la Consituciones Venezolanas de 1961 y 1999'(2000) 5 *Aldea Mundo* 9, 33- 37

⁷²⁵ Constitución de la República de Venezuela, enmienda publicadas en Gaceta Oficial N° 3.357 Extraordinario publicado el 2 de Marzo de 1984. Artículo 128 "Los tratados o convenios internacionales que celebre el Ejecutivo Nacional deberán ser aprobados mediante ley especial para que tengan validez, salvo que ... la ley atribuya expresamente al Ejecutivo Nacional..." Modification and translation by the author. Article 128 "International Treaties and Agreements subscribed by the President shall be approve via especial law as for them to have validity, except the cases where the area agreed upon belongs to a field reserved by the Consitution"

⁷²⁶ Gaceta Oficial Nro: 1620 01-11-1973, República de Venezuela, Párrafo Primero del Artículo único: "Las decisiones de la Comisión del Acuerdo de Cartagena que modifican la legislación Venezolana, o sean sobre material de la competencia del Poder Legislativo, requieren la aprobación

It is somewhat clear that Venezuela's Legislative Power was not interested in loosing or giving up its competences, which are reserved areas by law of this power. Even though the 1961 Constitution within Article 108⁷²⁷ favoured the Latin American integration process, committing its recourses in achieving common goals, any Treaty or community law required parliamentary approval before full implementation.

Thus, Hildegard Rondón de Sansó develops this theory when highlighting one important appeal on the ground of unconstitutionality presented before Venezuela's Supreme Court in 1982.⁷²⁸ This appeal demonstrated both the legislator's discomfort in transferring competences and jurisdiction from the national judge to the Andean Court of Justice, and also with community legislation to have direct implementation.⁷²⁹ In this respect, Marianela Zubillaba de Mejía, highlights that the Venezuelan Corte Suprema de Justicia, with this ruling gives evidence to the lack of constitutional framework to guarantee the integration process: there is no real competence attribution to communitarian bodies or institutions, there is no such thing as communitarian supremacy overriding national controls to approve community law and there is no direct implementation principle established within the constitutional framework.⁷³⁰

Following the discussion about impossibilities for community law to have direct implementation in Venezuela, Brewer Carías highlights that after the Supreme Court's aforementioned ruling all decisions related with the Cartagena's Agreement Commission having an impact on inland legislative areas needed approval via formal law by the Congress. Also he points out that those which were not approved did not have any validity in the country, in accordance with national law, in practice until 1992,⁷³¹ such as Decisions 85 and 311 related to community IP regime.

A shift in favour of the integration process became noticeable from 1992 onwards, when as it will mentioned below, the President began approving community law by ordering its immediate publication in *Gaceta Oficial* without the need for

mediante Ley del Congreso de la República" Original text in Spanish, translation above by the author

⁷²⁷ Constitución de la República de Venezuela, enmienda publicadas en *Gaceta Oficial* N° 3.357 Extraordinario publicado el 2 de Marzo de 1984. Artículo 108 "La Republica favorecera la integracion economica latinoamericana. A este fin se procurara coordinar recursos y esfuerzos para fomentar el desarrollo economico y aumentar el bienestar y seguridad communes." Translation by the Author. Article 108 "The Government will give priority to the Latinametican economical integration. Therefore, efforts and coordination of resources will be assigned as to promoto economic development, and increase both well-being and common safety"

⁷²⁸ Rondon de Sansó, H., *El Régimen de la Propiedad Industrial* (Editorial Arte, Caracas: Venezuela- 1995) at 24

⁷²⁹ Pérez Navarro, L., 'Los Principios Básicos del Derecho Comunitario' at 33-37

⁷³⁰ Zubillaga de Mejía, M., 'Sentencia del Caso José Andueza vs. Ley Aprobatoria del Acuerdo de Cartagena' in 61 *Revista de Derecho Público* 62 (Editorial Jurídica Venezolana -Caracas: Venezuela, 1995) 519-522

<www.ulpiano.org.ve/revistas/bases/artic/texto/RDPUB/61-62/rdpub_1995_61-62_519-522.pdf> accessed 14 September 2013

⁷³¹ Brewer Carías, A., 'Implicaciones Constitucionales del Proceso de Integración en la Comunidad Andina' Estudio para el Proyecto del Instituto de Estudios Internacionales (IDEI) de la Pontificia Universidad Católica del Perú, Perú, 2002.

Congress approval; i.e. Decisión 313 - Régimen Común sobre la Propiedad Industrial.⁷³²

Furthermore, in 1997 within Proceso N° 03-AI-96 that dealt with import barriers on coffee from Colombia, it addressed the breach of the Cartagena agreement by Venezuela. In this case the Andean Community Court highlighted that Article 27 from the Agreement creating the Court recognised the supremacy of community law over any national law, since otherwise the idea of having a “Community” is just inadmissible and continued defining the transfer of powers from the national judge to community judge for all matters related to community interests.⁷³³ Thus, amending the national constitution was deemed necessary as highlighted by some scholars.⁷³⁴ Finally, in 1999 Venezuela’s Constitutional framework was amended in favour of the integration agreement. Article 153 specifically grants direct implementation of community law within the national framework.⁷³⁵

5.6. Andean Intellectual Property Regime

Intellectual property rights, as for any other integration agreement, played an important role within the life of the Andean Pact. Thus, as early as 1971, the first community IPR regime came in force, specifically “Régimen Comunitario de Tratamiento a los Capitales Extranjeros y sobre Marcas, Patentes, Licencia y Regalías.”⁷³⁶ Accordingly, the Cartagena Agreement aimed to achieve in specific periods of time diverse agreements, but these goals were not met, except in the case related to IPR where article 27 from the agreement specifically draws a deadline for such a regime to be published and implemented by its member states.⁷³⁷ This regime is deemed emblematic, given that regulated specific areas

⁷³² Idem, and See also Gaceta Oficial N° 4.284 from 28 June 1992

⁷³³ Proceso N° 03-AI-97, original text in Spanish “a propósito de la interpretación del artículo 27 del Tratado del Tribunal, al considerar que para la existencia del derecho de la integración es indispensable el reconocimiento del principio de supremacía o prevalencia sobre el derecho interno de los países miembros; la misma sentencia define el tránsito de la competencia reguladora nacional hacia la comunitaria en los asuntos cuya decisión corresponde a esta última, como el desplazamiento automático de competencias, que pasan del legislador nacional al comunitario.”

⁷³⁴ Zubillaga de Mejía, M., ‘Sentencia del Caso José Andueza’, at 520

⁷³⁵ Constitución de la República Bolivariana de Venezuela, Gaceta Oficial del 30 de Diciembre de 1999, N° 36.860. Article 153 “those legal norms adopted within the frame of international agreements will be considered as integral part of the national legal system, having direct and preferred implementation into national legislation” Original version in Spanish, translation provided by the author. Artículo 153: “...Las normas que se adopten en el marco de los acuerdos de integración serán consideradas parte integrante del ordenamiento legal vigente y de aplicación directa y preferente a la legislación interna.”

⁷³⁶ This was the first community IPR regime for the Andean Pact and besides IPRs also dealt with foreign investments as derived from its name in Spanish. “Foreign Capitals and trademarks, Patents, Licenses and Royalties Common Regime” also known as Decision 24.

⁷³⁷ Artículo 27 Cartagena Agreement “Before 31 December 1970 the Commission, by the Board’s mandate, shall approve and consult with member states a community regime for Foreign Capitals, trademarks, Patents, Licenses and Royalties. Each Member State commits in implementing and amending its internal legislation within a six months from the approval of such regime, as for this to become in practice” ... “Antes del 31 de diciembre de 1971 la Comisión, a propuesta de la Junta, aprobará y someterá a la consideración de los Países Miembros un régimen común sobre el tratamiento a los capitales extranjeros y entre otros, sobre marcas, patentes, licencia y regalías. Los

are based on international criteria for transfer technology contracts and licences. Thus, the use of foreign brands and technology transfer sought to develop the national manufacture industry that represented national capitals, instead of foreign capital developing other industries such as oil and mining.⁷³⁸

Following Andean Community Decisions, they aimed to harmonise the standards of protection while at the same time complying with international ones. Several decisions have been enacted since the birth of this organisation, but for the purpose of this work, only those relevant during Venezuela's membership will be taken into consideration. Focus in particular will be on Decision 486, which was in force at the time of the withdrawal, and the current applicable IP Law from 1955.

The Rules for the implementation of the Norms of Intellectual Property - Reglamento para la Aplicación de las Normas sobre Propiedad Industrial - also known as Decision 85 which were enacted by the Cartagena Agreement Commission in extraordinary sessions from 27 May - 5 June 1974, despite the fact that this had to come into force within a period of six months in Venezuela, Decision 85 was never implemented.⁷³⁹ Accordingly, this decision modified substantially the internal IP regime and required changes to both legislative and administrative structures. Furthermore, economic sectors closely related to the IP sector seemed to have played an important role, since allegedly their patent rights were affected in a negative manner due to controls and limitations to work with them, and together with the crisis itself within the Andean Pact structure, they were determinant factors in Venezuela is regarding this Decision's implementation.⁷⁴⁰ It must be remembered that the Andean Pact faced a period of uncertainty during the 70s, among many things, due to Chile's withdrawal and the slowness in regulating the integration procedure itself.⁷⁴¹

In 1991 the Andean Commission reformulated the intellectual property regime first in Decision 311, which was never published in Venezuela even when elaborated in Caracas on 8 November 1991,⁷⁴² and then in Decision 313.

5.6.1. Andean Community Decisions 313

The latest community regime settled in Decision 313, enacted by the Andean Commission on 12 December 1991 superseded Decision 85. Accordingly, this binding resolution should have been immediately implemented in each country

Países Mienbros se comprometen a adoptar las providencias que fueren necesarias para poner en práctica este régimen dentro de los seis meses siguientes a su aprobación por la Comisión" (Datos del acuerdo agregar)

⁷³⁸ Kresalja Rosselló, B., 'La Política en Materia de Propiedad Industrial en la Comunidad Andina' *Separata del Libro Derecho Comunitario Andino* (Lima: Perú - 2003) at 241

⁷³⁹ Rondón de Sansó, H., 'La Decisión 313 de la Comisión del Acuerdo de Cartagena y el Régimen de Propiedad Industrial' (Caracas-1993) 13- 190, at 22

⁷⁴⁰ For further insight about the rationale behind Decision 85 non-implementation in Venezuela, see Rondón de Sansó, H., *La Situación Actual de la Propiedad Industrial: Venezuela-Noviembre 2008* (Editorial Litoformas, Caracas-2008) 1-266, at 23-24

⁷⁴¹ Rondón de Sansó, H., *La Situación Actual*, at 24

⁷⁴² Hildegard Ronsón de Sansó, *El Régimen de la Propiedad Industrial* (Editorial Arte, Caracas - 1995) 1-401, at 39

member once published within the Official Journal of the Agreement. However, the government did not acknowledge the Andean mandate and instead of approving it via formal law or approbatory decree, it was published in *Gaceta Oficial* N° 4.457 Ext. del 5 de Agosto de 1992.⁷⁴³

This brings to the spotlight a disparity in the criteria used when implementing community law. On the one hand, parliamentary approval is required, but on the other this decision was approved *de facto* since its publication was ordered without following the normal approval procedure. Hence, giving legal effects inside the country. In other words, and following Hildegard Rondón de Sansó's line of thinking, there was no clear understanding about the implications for the country in implementing community legislation even though some jurists moved forward petitioning for an unconstitutional action before the Supreme Court, as highlighted above.

Andean Community Decision 313 is of particular interest for the pharmaceutical industry in Venezuela. Following the discussion on the supranational character of this organisation, the community regime supplemented the IP Law from 1955, which was restrictive in terms of patentable subject matters. Hence, the progressiveness embedded within the intellectual property regime recently established envisages in Article 7, part (d), the non-patentability of those pharmaceutical products included on the WHO list of essential medication.⁷⁴⁴

A shift in policy criteria was evident between the IP Law from 1955 and the regime in Decision 313. Several aspects are worth mentioning: patentable subject matter; non-patentable subject matters; and patent ownership, term of protection and the compulsory licensing regime. Inventions, discoveries and improvements on those previously highlighted were worthy of a patent certificate in accord with Article 1° and 2°⁷⁴⁵ from the 1955 law. Thus, Decision 313 introduced patentability requirements⁷⁴⁶ - industrial applicability, novelty and innovative - needed for an invention to obtain patent protection, which were not present within the previous national system.

⁷⁴³ Rondón de Sansó, *La Situación Actual*, at 26

⁷⁴⁴ Acuerdo de Cartagena, Decisión 313, Article 7 Non-patentable subject matters; (d) "...Inventions related to pharmaceutical products listed within the Essecial Medication List from the WHO...", Original version in Spanish, translation provided by the author. "Artículo 7 No serán Patentables: (d) Las invenciones relativas a productos farmacéuticos que figuren en la lista de medicamentos esenciales de la Organización Mundial de la Salud;y,"

⁷⁴⁵ Article 1 from Ley de Propiedad Industrial "This Law regulates inventors, discoverers and those introducing the creations, rights over creations, inventions or discoveries related to the industry; and producers, manufacturers or merchants rights over phrases or special sings used to distinguish their works from similar ones." and Article 2: "The State will provide certificates of registration to trademark, slogan and commercial denomination owners, and patent certificates to owner for inventions, improvements, models and industrial drawings, and to those introducing inventions or improvements also registered."

⁷⁴⁶ Decision 313 – Regimen Común Sobre la Propiedad Industrial, Comisión del Acuerdo de Cartagena, Artículo 1° Member Countries will grant invention/product patents for inventions with industrial applicability, novelty and innovatieve. Original version in Sarnish, translation provided by the author. Artículo 1° Los Países Miembros otorgarán patentes de invención a las creaciones susceptibles de aplicación industrial, que sean novedosas y tengan nivel inventivo"

The second aspect to be mentioned relates to non-patentable subject matters, which in light of the IP Law from 1955 extended to all kinds of medicines and formulations, reactions and chemical combinations.⁷⁴⁷ This is in contrast to Article 7 (d) from Decision 313 that limits the scope to solely the medicines listed within the List of Essential Medicines – WHO. This provision could be seen as a ground-breaking one, given that developing countries could benefit from limiting the scope of protection for determined medicines without completely banning medicines' patentability. The third shift related to patent ownership, which substantially varies from one framework to another. Within the IP Law from 1955, ownership was given by assumption to the person in whose name the patent was registered.⁷⁴⁸ In contrast, Decision 313 in Article 8, establishes the possibility for legal or natural persons to claim ownership over an invention, but nevertheless patent rights belong to the inventor or its successor.⁷⁴⁹

The term of protection is another aspect worth mentioning, since it varies from the national to the community one. In the light of Article 9 of the IP Law from 1955, patent protection will be granted for a period of up to 10 years, whereas the term of protection in Decision 313 is extended to 15 years with the possibility to prolong it for another 5 years.

Another interesting feature brought by Decision 313 was the possibility to grant compulsory licences in determined cases, whereas the IP Law from 1955 omits this legal mechanism to correct competitive practices or solve national crises.⁷⁵⁰ In the light of the national law, not working a patent for a period of two years following patent grant will give enough grounds for the revocation of patent rights, but in Decision 313 a compulsory licence not only corrects the situation but also has a wider window of opportunity to work the patent in terms of time – 3 to 4 years depending on the case.

One particular point of interest in this Decision is the protection for pharmaceutical products. In an attempt to reach a resolution that would please both the pharmaceutical industry and the national pharmaceutical industry,⁷⁵¹ Decision 313 included two provisions destined to protect patent rights and access to medicines. Article 7 (b) excluded from patentability those inventions related to pharmaceutical products listed within the WHO charter of essential medicines, and the third transitional provision leaves to the discretion of each country member whether or not to exclude pharmaceutical products from patentability, even when these are not listed. Accordingly, the patent will be prohibited for a

⁷⁴⁷ Article 15, ord 1º from Ley de Propiedad Industrial

⁷⁴⁸ Article 3º from Ley de Propiedad Industrial

⁷⁴⁹ Dec. 313, Article 8º “Either legal or natural persons are entitled to patent ownership. However, patent rights belong to the inventor or its successor” Original text in Spanish, translation provided by the author. Artículo 8º “ Los titulares de las patentes podrán ser personas naturales or jurídicas. El derecho a la patente pertenece al inventor o a su causahabiente”

⁷⁵⁰ See Article 42 from Decision 313

⁷⁵¹ Rondón de Sansó, H., highlights the efforts from the “Junta de la Comisión del Acuerdo de Cartagena” in providing an obscure and complicated Decision that pleases both the pharmaceutical industry and the national pharmaceutical industry. Each side of the industry lobbied in its favour: the generic did not agree with the protection of pharmaceuticals since it did not have to pay for royalties, and the pharmaceutical industry stressed the need to protect their inventions. For a better insight, see Rondón de Sansó, Hildegard, “La Decisión 313 de la Comisión del Acuerdo de Cartagena y el Régimen de la Propiedad Industrial” (Caracas-1993) 1-190, at 51-52, 97

maximum period of 10 years after the Decision came into force, or the time established in the national law, not later than the 15 February 2002.⁷⁵²

From the aforementioned transitional provision it is important to highlight the complementary character given to national law, in this case, to Venezuela's IP Law from 1955. On the one hand this law is considered as complementary to the rules settled in Decision 313. But on the other, and given the nature of Decision 313, scholars have suggested that this abrogates national law since it establishes lower standards of protection than those provided in the Andean framework. In this respect, Rondón de Sansó, stresses that even though the national law coexists with community law, if there are provisions colliding with one another then community law prevails over national law, therefore abrogating it.⁷⁵³

Decision 313 contradicts the national patentability threshold, particularly in the field of pharmaceutical patents. The IP Law from 1955 specifically prohibits patents for these kind of inventions, hence, the contradiction and the supplementary character of community norm suggests that the standards of protection were those of Decision 313 and not the national law. Given this issue's complexity, the then President by virtue of Article 190 part 10 from the Constitution regulated in Decreto N° 2.887 the Decision itself.⁷⁵⁴ However, this legal framework swiftly changed into Decision 344, reforming the IP system.

5.6.2. Andean Community Decision 344

After regulating on 15 April 1993 the Decision 313, later that year on 20 October a new reformulation on the community intellectual property regime was announced and published in the Official Journal of the Cartagena Agreement. Decision 344 only regulates the IP system in general; specific provisions, namely the Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties, were given in a separate framework, Decision 345 that will not be analysed within the present work.

As with the previous decision, this one is part of a particular kind of law that implies direct and immediate application under a Constitutional framework that requires parliamentary approval.⁷⁵⁵ So far there are no clear answer on this matter; it has been argued that the important thing is to determine whether or not the law approving the Cartagena Agreement per se continues in force in Venezuela –at that time, 1995- or if the reform and posterior approval of the Agreement Protocol abrogated the last one.⁷⁵⁶

Despite the constitutional discussion, as established before, community law should be of preferential application in all country members. In this respect, Rondón de Sansó, stresses the importance of those “complementary provisions” contained within the Decision 344 itself. These, in Article 144, refer to national

⁷⁵² See Disposición Transitoria “Tercera,” Decisión 313, 6 February 1992, published in Gaceta Oficial de la República de Venezuela N° 4.457, Extraordinario del 5 de Agosto de 1992.

⁷⁵³ Rondón de Sansó, Hildegard, ‘La Decisión 313 de la Comisión del Acuerdo’, at 37-40

⁷⁵⁴ See Rondón de Sansó, H., El Régimen de la Propiedad Industrial: Con especial referencia a la Decisión 344 de la Comisión del Acuerdo de Cartagena (Caracas-1995) 1-401, at 50-52

⁷⁵⁵ See Article 139 from Constitución de Venezuela from 1961

⁷⁵⁶ Rondón de Sansó, H., El Régimen de la Propiedad Industrial, at 88

law for those cases not regulated in the community framework, such as determining which is the competent office to deal with intellectual property rights. “National Competent Office” and “National Competent Authority” are defined, even though the previous provision is not to be found in the complementary provisions, but only on the final provision from the Decision.⁷⁵⁷

This new reform began aligning with the minimum standards of protection that were later on settled in TRIPS. Thereafter, it is important to briefly assess the main differences between Decisions 313, 344 and IP Law from 1955 so as to provide a broader picture on the improvements or this ‘framework’s evolution under the Andean Community umbrella.

Both Decision 313 and 344 fail to provide a concrete definition for the term “invention;” in other words, there is neither a specific glossary of terms nor an article defining what constitutes invention per se. In this respect, scholars suggest as inventions those human creations that develop new products or processes destined to operate in the state of the art.⁷⁵⁸

The IP Law from 1955 also fails to provide such a definition, and instead a list of patentable and non-patentable subject matters is provided. Within the three legislations analysed so far, there are important differences. In Article 1 from Decision 344 it is expressly stated that member countries shall grant patents for inventions, both products and processes, in all fields of technology as long as these are new, involve an inventive step and are industrially applicable. Whereas Decision 313, Article 1 limits member countries to granting patents for “creations” industrially applicable, that is novel and involves an inventive step. Moreover, Article 2 specifically foresees patent protection for inventions, improvements, models or industrial drawings and introduction of improvements and inventions.

However, it has been argued the fact that discoveries are also patentable in the light of the IP law from 1955, which contradicts in the first instance Article 6 from Decision 344, where these are expressly non-patentable subject matters. Astudillo Gómez suggests the use of the word discovery as a synonym for inventions within the Venezuelan law. In this regard, the scholar proposes to accept that inventions withhold discoveries of not known scientific facts, which are or not transformed into an invention due to human intervention. Therefore, both concepts complement each other and could have the same conceptual value if industrial applicability is proven.⁷⁵⁹

⁷⁵⁷ This is an express case of community law referring to national law, as perhaps to avoid overlapping national competences. Therefore, determining national competences, entities and bodies relies solely in national law, in this case the IP Law from 1955. Accordingly the national competent office is SAPI or the National Registration Office, as known in the past, and the national competent authority is the Ministry of Development – Ministerio de Fomento- nowadays Ministry of Commerce – Ministerio del Poder Popular para el Comercio. See Decision 344, Disposición Final, Unica.

⁷⁵⁸ Rondón de Sansó, H., *El regimen de la Propiedad Industrial*, at 125. According to the scholar, the aforementioned concept can be deduced from the Decision itself and the articles listing patentable and non-patentable subject matters

⁷⁵⁹ Astudillo Gómez, F., *La Protección Legal de las Invenciones: Especial referencia a la biotecnología* (Colección Ciencias Sociales, Serie Jurídica, 1ra Edición, Universidad de los Andes, Mérida:Venezuela, 1995) 1-412, at 43-48

Another important difference between the Decisions and the national law relates to the term of protection, which significantly varies from one to the other. The Venezuelan law grants from 5 to 10 years of protection depending on the inventions and the owners request, Decision 313 granted 15 years of protection, and Decision 344 in Article 30 now grants 20 years of protection following the filing date.⁷⁶⁰

The starting point for the term of protection established in the Andean community framework differs from the one settled in the IP Law from 1955. Both Decision 313 and 344 start counting the term of protection following the filing date, but the national law starts computing it from the moment the patent certificate has been granted.

In relation to the compulsory licensing regime, both Decisions provide somewhat clear terms for sanctioning patents. Ultimately, in cases of national emergency, member countries shall grant via patent offices compulsory licences for the necessary period of time. Perhaps Decision 344 in Article 46⁷⁶¹ is more precise in delimiting terms and conditions for such a licence than Decision 313 Article 42. Nevertheless, the Andean framework envisaged a compulsory licensing regime to solve both anti-competitive practices and national emergencies, whereas the national regime entails expropriation of patents to correct these issues.

5.6.3. Andean Community Decision 486 and the TRIPS Agreement

As is widely known, in 1994 Uruguay achieved the Agreement on Trade Related Aspects of Intellectual Property, ratification and implementation that became compulsory for all those member countries wishing to accede the World Trade Organization.

The Andean Community of Nations, following the minimum standards of protection settled within the TRIPS Agreement, reformulated its common intellectual property regime, providing member countries with Decision 486 published in the Official Journal of the Cartagena Agreement in 19 September 2000.

Accordingly, Decision 486 came into force on the 1 December 2000. Thereafter, member countries came into compliance with the TRIPS Agreements in the same year. Scholars have denoted as an interesting fact the prompt compliance on behalf of this organisation integrating five developing countries.⁷⁶² Initially, least – developed countries had 10 years to come into compliance, and developing

⁷⁶⁰ Decision 344, Article 30: The patent shall have a term of 20 years following the filing date of the corresponding application.

⁷⁶¹ See Decision 344, Section VII – Licensing Regime, <www.sice.oas.org/trade/junac/decisiones/Dec344e.asp> accessed 20 February 2012

⁷⁶² Even when the scholar makes reference to the transitional period given to least-developed countries, according to the United Nations countries classification, no Andean Country member is listed within the least-developed nations at the U.N. Therefore, the applicable transitional period allowed was of 4 years instead of 10 years, unless as a developing country complied with Article 65 part 4 extending the transitional period for an extra 5 years. See, Mogollón-Rojas, I., 'The New Andean Pact Decision No. 486 on the Common Industrial Rights Regime' (2001) 4 *The Journal of World Intellectual Property*, 549-555 at 550

nations had one year to comply after the WTO Agreement came into force,⁷⁶³ unless the member country was “in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations” in which case Members could benefit from a transitional period of 4 years.⁷⁶⁴ Extensions to this initial transitional period could be taken on the basis of Article 65 (4), therefore allowing another 5 years to come into compliance with the aforementioned legislation. Whether or not member countries made use of this advantage to extend the transitional period, Andean Community Decision 486 ratified the possibility in claiming patents for products and processes in all fields of technology, as Decision 344 previously did.

Neither IP Law from 1955 nor community Decisions define inventions or patents for inventions. In all cases an enumeration on patentable subject matters and types of patents provide users, in between lines, with the concept for patent for inventions. In this respect, Astudillo Gómez suggests the former are certificates expedited by the Estate granting exclusive rights for a determined period of time to its inventors or right holders.⁷⁶⁵ The term of protection between this Decision and superseding one remains 20 years from the application date. Important differences are found within the national and the community framework, with the local one as also denoted above, granting 5 to 10 years of protection following the patent certificate and not from the filing date as granted in Decision 486.

The Common IP Regime follows the International Patent Classification established in 1971 by the Strasbourg Agreement Concerning the International Patent Classification, together with its effective amendments.⁷⁶⁶ Perhaps another important difference, given the consequences derived from it, refers to both the timeframe to work a patent and cases where failing to do so will not cease patent rights. Accordingly, the national law in Article 17 (c) foresees as justifiable cases where the patent holder effectively proves force majeure as the rationale behind not working the patent in those 2 years from the time the certificate was granted. Instead, Decision 486 defines in Article 60 what is to be understood as the working requirement, which can also be fulfilled by importing, distributing and commercialising the product in a sufficient manner to satisfy national market.⁷⁶⁷

The local working requirement is directly intertwined with the compulsory licensing regime established within Chapter VII contained in Decision 486. For instance, if the local market has not been supplied with the patented product in accord with Articles 59 and 60, any interested third party is entitled to work the patent. This prerogative is not *de facto*; on the contrary, the interested party needs to petition the competent authority –patent office– to enact such a licence, and the former needs to verify that the patent has not been exploited in a period of 3 years from the time it was granted or 4 years since the application date. On the

⁷⁶³ Article 65 and 66 from TRIPS Agreement, Initially least-developed countries had until February 2005 to comply with Trips, but later on this transition period was extended until 2016

⁷⁶⁴ Article 65(1) and (2) from TRIPS Agreement

⁷⁶⁵ Astudillo Gómez, F., *La Protección Legal de las Invenciones: Especial referencia a la Biotecnología* (Universidad de Los Andes – Universidad Gran Mariscal de Ayacucho, 2da. Edición, Mérida – 2004) 1-498, at 84

⁷⁶⁶ Decision 486, Article 49

⁷⁶⁷ See Decision 486 Article 59 and 60

other side, the third party needs to prove the efforts in obtaining a contractual licence from the patent holder to work the patent.⁷⁶⁸

In this respect, the national law is more restrictive given the local working requirement must be fulfilled within a period of 2 years, and this needs to take place in a determined geographical area, whereas community law allows to take into consideration the patent exploitation in not only one of the member countries but in all of them. In other words, if the patent product has been produced, commercialised or distributed in only one of the Andean countries it seems to be enough so as to fulfil the working requirement despite the insufficiency in satisfying another Andean country member's market.

A striking difference between national and community law refers to the grant procedure, in which the national law –as stated above- consists of claims without formal examination with call to formulate oppositions; whereas community law foresees formal examination⁷⁶⁹ with preliminary examination⁷⁷⁰ and call to formulate oppositions.⁷⁷¹

The opposition period in both frameworks grants 60 days following the publication within the IP Official Journal, with the only divergence relating to those enabled to contest patent claims. Decision 486, Article 42 provides that only those with a legitimate interest may contest the application, whereas in IP Law from 1955, Article 63 this “privilege” is extended to anyone wishing to contest it. Furthermore, as highlighted within the IP law from 1955 analysis, the opposition procedure as provided by that framework is decided either by administrative or judicial authorities depending on the nature of the opposition, whereas Decision 486 provides administrative authorities, specifically “competent authorities within the patent office”, to solve oppositions.⁷⁷² The timeframe when filing for opposition may be extended to 2 years right after the patent has been issued. If a third party wishes to oppose such a patent, it can do so before a court, possibly leading to invalidating the patent.⁷⁷³

Patent nullity or invalidating a patent in accord with Decision 486 can be declared *ex officio* by the national patent office or by third party petition. In either of the cases, the motivation behind patent nullity or invalidation can be summarised in the cases where patentability requirements are not either met or fulfilled, or because these are breached, or because this grant is against public

⁷⁶⁸ Decision 486, Article 61

⁷⁶⁹ Decision 486, Article 38 refers to the time given to the competent authority to examine the application, and Article 39 refers to the examination of form or formal examination

⁷⁷⁰ Decision 486, Article 44 established that an applicant should request the examination on the patentability 6 months after the first publication regardless of any opposition formulated to the patent claim

⁷⁷¹ Decision 486, Article 42 allows a period of 60 days following publication for anyone with a valid interest to contest (oppose) the patent claim, of course, the rationale for such opposition shall be provided.

⁷⁷² Rondón de Sansó, La Actual Situación de la Propiedad, at 164

⁷⁷³ Bazzani, H., and Pacheco, Carlos., ‘Venezuela: What next for industrial property as Venezuela leaves the Andean Community’ *Building and Enforcing Intellectual Property Value 2010* (IP Value – An International Guide for the Boardroom, 2010) 105-108
<www.iam-magazine.com> accessed 2 April 2012

order or interest.⁷⁷⁴ Patent and patent application lapses within this legal framework when annual fees are not paid for in the timeframe given in Article 80.⁷⁷⁵ In contrast, the national law provides patent invalidation and/or nullity not only for unpaid administrative fees, but also when this was granted against a better right, which needs to be ruled by a court.

Besides those aforementioned differences between legal frameworks, the compulsory licensing regimes significantly differs from each other, given that these are not foreseen within the national framework.

Accordingly, compulsory licences are not only to correct anti-competitive practices. Another important use is to address health emergency crises and/or national emergencies. Hence, Article 65 from Decision 486 settles the conditions for these to be enacted. Within the Andean regime, a compulsory licence, due to public interest –e.g. national emergencies–, will last for as long as the rationale to enact it exists, and this provision also stresses the patent holder's right to keep on making use of his/her patent rights while third parties make use of the originators right to solve a specific situation.⁷⁷⁶

When analysing the national IP law from 1955, it was stated the fact that once patent rights are affected with public interest these will be expropriated, and passed into the public domain. Under this legal framework, patent holders lose patent rights given that once patent rights have been expropriated by the State patent owners will no longer be able to produce, distribute or commercialise their product regardless of the duration of the national emergency.

Whereas the Andean Community regime foresees the use of compulsory licences for four different scenarios,⁷⁷⁷ which are not limited to national emergencies, namely for breaching the local working requirement, previous declaration of national emergency on behalf of a member country, to correct anti-competitive practices, and as a necessary element to work a posterior patent.

5.6.4. Venezuela's withdrawal from the Andean Community: Legal Consequences⁷⁷⁸

The Venezuelan Government, on the 22 April 2006, denounced the Andean Integration Sub-regional Agreement before the President of the Andean Community Commission. Venezuela's withdrawal from the Andean Community was founded on the ratification of the U.S-FTA with Colombia and Peru who are still CAN member States. Even though all other Andean Community Members did not oppose Colombia and Peru from negotiating such an agreement, Venezuela did express its concerns in terms of the impact that this FTA with the U.S. would have on the remaining trading partners despite them not having

⁷⁷⁴ Decision 486, Articles 14,15 and 20

⁷⁷⁵ Decision 486, Article 75 – 80

⁷⁷⁶ Decision 486, Article 65

⁷⁷⁷ See further Rondón de Sansó, '*La Situación Actual de la Propiedad*', at 134-135

⁷⁷⁸ Parts of this analysis were also mentioned by Cadillo Chandler, Dhanay; and González Otero, Begoña, "Legal Certainty, TRIPS and Venezuela on the matter of patents and trade marks: What has happened?" submitted for publication at IIC Journal in February 2012. (Pending acceptance)

subscribed to such FTA. In other words, Venezuela feared imposition of higher standards of protection by CAN.⁷⁷⁹

With the withdrawal, Venezuela aimed at protecting national interests. However, this decision brought along a set of challenges that needed to be addressed so as to ensure the normal development of subsequent trading operation among the former trading partners. Namely, determining the precise time when the link between CAN and Venezuela ceased to exist, and if and for how long ACN's framework and binding decisions were applicable in Venezuela once the withdrawal was formalised.⁷⁸⁰ To solve the first question, scholars suggested the need to consult, or even apply if possible, the principles set forth within the Vienna Convention on the Law of Treaties from 1969. They did, however, stress the fact that rules are only applicable as general principles of public international law since Venezuela has not ratified its adherence to the Convention.⁷⁸¹

To address the validity timeframe for Venezuela to keep on applying or be subject to both ACN framework and binding decisions, it is then necessary to consult the Cartagena Agreement (as modified in Decision 406). In this respect Article 153 provides:

Any Member Country wishing to denounce this Treaty shall so inform the Commission. From that moment on it shall cease to enjoy the rights and have the obligations deriving from its status as Member, with the exception of the benefits received and granted in accordance with the Sub-regional Liberalisation Programme, which shall remain effective for a period of 5 years after the date of the denouncement.

The time period stipulated in the paragraph above may be shortened in duly substantiated cases by decision of the Commission and at the request of the interested Member Country.

Insofar as the Industrial Integration Programmes are concerned, Article 62 paragraph I) shall be applied.⁷⁸²

In light of the Cartagena Agreement, Venezuela was to continue applying Andean regulations for a period of 5 years. In accord with the Vienna Convention's Article 70.2, applicable to this case because Venezuela was denouncing a multilateral treaty and because the Cartagena Agreement did not foresee otherwise, the former Andean Community member's duties and obligations ceased to exist once formalising the denouncement procedure. Nevertheless, the rights, obligations or legal situation of the parties created through the execution of the treaty prior to its termination continue to exist⁷⁸³ for a period of 5 years after formalising the

⁷⁷⁹ Prensa Vicepresidencia "Texto de la carta donde Venezuela denuncia acuerdo de Cartagena y se retira de la CAN" Newspaper <www.aporrea.org/tecnologia/n76531.html> accessed 9 January 2012

⁷⁸⁰ Rondón de Sansó, *La Situación de la Propiedad Industrial* (Lito-Formas, Caracas 2009) at 78

⁷⁸¹ Ibid Rondón de Sansó at 79

⁷⁸² Art. 153 of de Cartagena Agreement: "Any Member Country wishing to denounce this Treaty shall so inform the Commission. From that moment on it shall cease to enjoy the rights and have the obligations deriving from its status as Member, with the exception of the benefits received and granted in accordance with the Sub regional Tariff Reduction Programme, which will remain effective for a period of 5 years after the date of the denouncement."

⁷⁸³ Vienna Convention on the Law of Treaties from 1969. Article 70: Consequences of the termination of a treaty: 1. Unless the treaty otherwise provides or the parties otherwise agree, the termination of a treaty under its provisions or in accordance with the present Convention: (a) releases the parties from any obligation further to perform the treaty; (b) does not affect any right,

withdrawal when taking into consideration the aforementioned Article 153 from the Cartagena Agreement.

The intellectual property rights framework settled within Decision 486 was also believed to enjoy those 5 years of validity posterior to the withdrawal. With the Memorandum of Understanding (hereinafter M.O.U.)⁷⁸⁴ signed and published in Decision 641, the parties committed in applying the Andean regulatory framework during the 5 years agreed upon a transitional period in order to safeguard trading activities.⁷⁸⁵ In this respect, the Andean Court of Justice in proceeding N° 2-AI-2006 ratified the 5 years period of time given to any country member to enjoy and maintain the right to import and export duty and restriction free, all those products originated in any of the other members.⁷⁸⁶

Decision 486 continued ruling up to 2008, until SAPI published in an Official Note, dated 12 September 2008, that Decision 486 was no longer applicable, thus re-enacting Venezuela's IP Law from 1955. The patent office, in principle, has no legislative faculties to abrogate and re-enact laws. This *de facto* shift of regulatory frameworks preoccupied Venezuelan scholars and practitioners, since the validity of the IP Law from 1955 was questionable. On 5 November 2008, SAPI in Bulletin N° 497 dismissed a petition to suspend the legal effects of the Official Note from 12 September 2008.⁷⁸⁷ Before re-enacting the aforementioned law, it was important to determine whether or not this IP Law from 1955 had actually been abrogated or partially abrogated by Decision 344 and previous ones, since these became part of the internal legislation.

SAPI's rationale for not overturning its Official Note was relayed in an Andean proceeding from 25 May 1988 (Proceso N° 2-IP-88). It argued against the validity of Decisions 344 and 486 since the patent office considered that the aforementioned framework only temporarily suspended the IP Law from 1955 by virtue of the direct and preferment treatment given to the community. Furthermore, SAPI also suggested that the implementation of those Decisions issued by the Andean Commission⁷⁸⁸ only derived from an international

obligation or legal situation of the parties created through the execution of the treaty prior to its termination. 2.

⁷⁸⁴ Memorandum of Understanding – also known as M.O.U.- often sets out operational arrangements under a framework international agreement and it can also be used to regulate technical or detailed matters. See United Nations, "Treaty Handbook" 55 (United Nations Publication, 2006)

⁷⁸⁵ SainzBorgo, J., in his article 'La Salida de Venezuela del CAN' 30*Politeia*28, 127-150 seems to suggest that this M.O.U subscribed new international obligations for the parties, which in first place was not the rationale motivating Venezuela's withdrawal from the Organisation.

⁷⁸⁶ Tribunal de Justicia de la Comunidad Andina, Proceso CAN N° 2-AI-2006 de 13 de Julio de 2006, Secretaria General de la Comunidad Andina vs. República Bolivariana de Venezuela: Accion of *assumpsit* (accordingly with common law or civil enforcement action in civil law) for breaching the principle of national treatment in terms of import tariffs.

⁷⁸⁷ SAPI – Boletín N°497

<www.sapi.gob.ve/images/stories/contenido/boletines/Boletin_597.pdf> accessed 9 January 2012

⁷⁸⁸ The Andean Community Commission is the main policy making body and the Andean Community Court of Justice is the judicial body, which has territorial jurisdiction in the four countries as well as being the only body that actually can interpret community law and settle disputes among member states or derived from community law. Hence, the binding character embedded in all of its Decisions and rulings. See Andean Community, Andean Court of justice

obligation which ceased to exist once the Agreement was denounced, thus, could not be considered as real law or part of internal law and could even abrogate national laws.⁷⁸⁹

Even though SAPI quotes a proceeding from 1988 to interpret the principle of preferred treatment in community law, this interpretation seems to be erroneous for two reasons. Firstly, SAPI lacks the competence to fulfil interpretation tasks, and secondly the only authority competent to interpret the principles within the Cartagena Agreement is the Andean Court of Justice. However, following Venezuela's withdrawal, SAPI prior to its Official Note continued applying the Andean regulation as a referential framework.

Another interesting fact from SAPI's interpretation is that the Constitution from 1999, which was in force at the time of the withdrawal, enshrined direct and preferred treatment in an attempt to favour integration processes.⁷⁹⁰ To implement community law it is necessary to have a real transfer of both power and jurisdiction to community bodies. Nevertheless, Venezuelan authorities seemed reluctant to give up competences, as several court rulings from the Supreme Court portrayed previous years.⁷⁹¹

In terms of the Andean Community norm implementation tradition in Venezuela, scholars have highlighted a few disparities that could influence one way or the other how SAPI interpreted the applicability of Decision 486 after the withdrawal. The first resolutions harmonising intellectual property rights were Decision 84 and 313, which received presidential approval in 1992 when their publication was ordered by the President so as to have immediate effect in national law. Nonetheless, Decision 84 was never implemented in Venezuela because it was neither sanctioned by the Congress nor approved by the President.

The challenging issue when SAPI disregarded Decision 486 relates to the legal hierarchy involved as it deals with Human Rights. In accord with the Venezuelan Constitution's Article 23, treaties, pacts and conventions on human rights ratified by the country receive constitutional status. Intellectual property rights,⁷⁹² as pointed out a few headings above, are enshrined within the Constitution's human

⁷⁸⁹ SAPI – Boletín N° 497

⁷⁹⁰ Constitución de la República Bolivariana de Venezuela, Gaceta Oficial del 30 de Diciembre de 1999, N° 36.860. Article 153 “those legal norms adopted within the frame of integration agreements will be considered as integral part of the national legal system, having direct and preferred implementation into national legislation” Original version in Spanish, translation provided by the author. Artículo 153: “...Las normas que se adopten en el marco de los acuerdos de integración serán consideradas parte integrante del ordenamiento legal vigente y de aplicación directa y preferente a la legislación interna.”

⁷⁹¹ See, Tribunal De Justicia de la Comunidad Andina, proceso N° 03-AI-96 del 24 de Marzo de 1997, and also See, Ventata, V., ‘Estudio de la Sentencia Galleries Lafayette’(1993)90 *Revista de la Facultad de Ciencias Jurídicas y Políticas*, 226 – 255

⁷⁹² Constitución de la República Bolivariana de Venezuela de 1999. “Article 98° cultural creation is free. This liberty foresees the right to invest, produce and divulge a literary creation, a scientific, technological and human one, including legal protection for authors over their works. The State shall recognise and protect intellectual property rights for scientific, literary and artistic inventions, innovations, indications, patents, trademarks, slogans according with the conditions and exceptions established by law given by International treaties, related to the topic, ratified and subscribed by the Republic.” Translation by the Author. Original text in Spanish.

rights chapter, and hence they have a supra-national rank that allows them to enjoy direct and immediate implementation.⁷⁹³

SAPI's official notice re-instating the IP Law from 1955 contributed to the already existing legal uncertainty. Moreover, scholars have not only questioned the patent office's competence to re-instate legislation, but also which is right procedure to re-enact the aforementioned IP Law. Two suggestions have been widely discussed: on the one hand, it has been argued that only the National Assembly should have abrogated Decision 486 by enacting a law reinstating the IP Law from 1955.⁷⁹⁴ Thus, drafting a law that copes with minimum standards of protection. And, on the other hand, it has also been argued that regardless of how the Andean IP framework was abrogated and the old one reinstated, the new legislation should have been drawn up to comply with the minimum standards of protection.⁷⁹⁵ Both suggestions address the issue of compliance with TRIPS since Venezuela belongs to the World Trade Organization. The Supreme Court's Appellate Chamber formally dismissed the applicability of Decision 486,⁷⁹⁶ portraying the existent division between scholars and the judicial system. This court ruling contradicts the transitional period set forth within the M.O.U.; the Court highlights that Decision 486 was only applicable for a period of 180 days after the withdrawal. Practitioners have emphasised the legal limbo that Venezuela's intellectual property regime has been placed in with this court ruling and also by the fact that SAPI continued applying Decision 486 well past the aforementioned 180 days.⁷⁹⁷

5.7. Can MERCOSUR improve Venezuela's current Intellectual Property system?

Besides its membership within the Andean Community of Nations, Venezuela pursues full membership of MERCOSUR (Mercado Común del Sur – Southern Common Market). The Treaty of Asunción, signed on 26 March 1991, created this integration organisation that was inspired by similar principles settled within the European Community.

⁷⁹³ Idem, Article 23: Treaties, pacts and conventions relating to human rights which have been executed and ratified by Venezuela, have constitutional rank and prevail over national legislation as long as they contain provisions concerning the enjoyment and exercise of such rights that are more favourable than those established by this Constitution and the laws from the Republic, and are of immediate and direct application by Courts and other organs from the Public Power.

<www.unhcr.org/refworld/category/LEGAL/,,VEN,4c45ad8b2,0.html> accessed 20 January 2012

⁷⁹⁴ Carrascosa de Mena, J.M., 'Notas sobre la involución en el derecho de marcas venezolano' *El Universal* 25 August

2009 <www.marcasur.com/es/opinion_resultado.asp?NoNoId=1245> accessed 4 January 2012

⁷⁹⁵ Rondón de Sanso, H., 'Ex magistrada propuso la redacción de ley de propiedad industrial para desplazar a Eduardo Samán del Gobierno' Observatorio Sudamérica de Patentes, 6 September 2011, available at: <www.aporrea.org/tecno/n188101.html> accessed 4 January 2012

⁷⁹⁶ See Anchor Fasteners, C.A. contra Anclajes Powers, C.A. in Sala de Casación Civil, Tribunal Supremo de Justicia, República Bolivariana de Venezuela, Expediente N° 2010-000465

⁷⁹⁷ see Antequera Parilli, R., 'Tribunal Supremo de Justicia de Venezuela declara la inaplicación de la norma andina en propiedad industrial' (13 April 2011) *Artículos de Estudio Antequera Parilli & Rodríguez* <www.antequera.com.ve/index.php?mod=articles&exec=detail&id=227> accessed 10 April 2014

Argentina, Brazil, Paraguay and Uruguay founded the organisation based on reciprocity, respect for each other's sovereignty and free market.⁷⁹⁸ Later on in 2006 Venezuela signed the Protocol of Adhesion to Mercosur, which comes into force in accord with the ratification rules settled in the aforementioned Treaty, and Venezuela's Adhesion Protocol.⁷⁹⁹ To this date, Paraguay is still pending Venezuela's ratification within the organisation, despite the fact that this country has the right to take part in all negotiations and meetings concerning MERCOSUR. In accord with the Consejo de Mercado Común (Council of the Common Market – CMC), Venezuela was not a full member country until recently; therefore it only has the right to be heard, but not to vote.⁸⁰⁰

This organisation will not be analysed in depth given that it is not as relevant as the Andean Community's framework, when assessing access to medicines. However, it is important to highlight certain aspects related to intellectual property rights, specifically patent rights within Mercosur.

Despite the fact that trade is regulated, and to a certain extent harmonised, within the organisation there is not an intellectual property regime conceived as in the Andean Community. In this respect, there are only two Protocols signed, but not yet in force, to regulate trade names, appellations of origin and denomination of source, and another one regulating industrial drawings.⁸⁰¹ Therefore, patents are left to be regulated by each country's own legislation, as long as the territoriality principle is followed.⁸⁰² Article 2 in both Protocols elaborates on the validity of member countries' international commitments, demanding compliance with the norms and principles settled in both the Vienna Convention and the TRIPS Agreement. Furthermore, MECOSUR Decisions could be regarded as Directives from the European Community,⁸⁰³ and provide within the first article the commitment on behalf of the member countries to effectively protect those intellectual property rights regulated within the protocol, allowing at the same time higher standards of protection as long as these do not collide with the ones settled in the Protocol. Hence, like TRIPS, they settle minimum standards of protection.⁸⁰⁴

⁷⁹⁸ Article 1 and 2 Tratado para la Constitución de un Mercado Común entre la República Argentina, República Federativa de Brasil, República de Paraguay y la República Oriental de Paraguay

⁷⁹⁹ Accordingly, prospective member countries wishing to become full members will do so thirty days after the fifth ratification instrument has been deposited. Article 12 Protocolo de Adhesión de la República Bolivariana de Venezuela al Mercosur, and Article 20 from the Treaty of Asunción

⁸⁰⁰ See further Reporte del Grupo de Trabajo Ad Hoc, MERCOSUR/V CMC EXT./DI N° 04/07 <www.mercosur.int/msweb/SM/Actas%20TEMPORARIAS/CMC/V%20ext%20CMC%2001%20_%2007/AnexoVI_InformeGT-VENE.pdf> accessed 20 December 2012. See also footnote 2 at the document XXXVI REUNIÓN DEL CONSEJO DEL MERCADO COMÚN DEL MERCOSUR <www.ciu.com.uy/innovaportal/file/752/1/cumbre_mercosur_xxxvi.pdf> accessed 20 December 2012

⁸⁰¹ Protocol of Harmonisation Norms on Intellectual Property in Mercosur in matters of trade marks, indications of source and appellation of origin, Dec. No. 08/95, signed in Asunción, 5 August 1995, and Harmonization Protocol of norms on Industrial Design, Dec. No. 016/1998, signed in Rio de Janeiro, 10 December 1998

⁸⁰² Rondon de Sansó, H., 'La situación de Actual de la Propiedad' at 177

⁸⁰³ Ibid at 176

⁸⁰⁴ See further, Art. 1 from Protocol of Harmonisation Norms on Intellectual Property in Mercosur in matters of trade marks, indications of source and appellation of origin, Dec. No. 08/95, signed in

Scholars have addressed the need for further norm harmonisation on matters related to patent rights. Specifically, the patent regime should clarify aspects such as: patentability, exhaustion of rights, compulsory licences, term of protection and renewal of it, scope of protection, exclusive rights exceptions, parallel imports and patent nullity among several other aspects. This scholar stressed that member countries are left with the option of legislating over these matters with certain freedom, taking into consideration that TRIPS only establishes minimum standards of protection. Therefore, it is fundamental in her view to harmonise patentability, exhaustion of rights, compulsory licences and term of protection.⁸⁰⁵

In this respect, it is important to mention the fact that Venezuela is currently heavily dependent on imports from Mercosur member countries, while at the same time becoming a large energy and oil/derivate exporter. This energy cooperation belongs to the energy cooperation between Argentina, Brazil, Uruguay and Venezuela under the Petroamérica project, which includes a natural gas pipeline to supply the Brazilian market among other initiatives.⁸⁰⁶ Medicines are among the goods imported by Venezuela, thus, considering the current applicable law in Venezuela that breaches TRIPS and other international agreements, it deems essential to harmonise the patent regime to contribute to the country's legal certainty within the field of intellectual property rights.

Despite de fact that patents are not regulated within MERCOSUR, trademarks are, thus parties are deemed to comply with the Nice International classification system if already not implemented.⁸⁰⁷ Therefore, the reinstatement in Venezuela of the IP Law from 1955 was thought to place Venezuela in a borderline situation when aspiring to become a full Mercosur member country,⁸⁰⁸ which in the end it did not.⁸⁰⁹

Perhaps the linking point between the Andean Community legislation and MERCOSUR relates to the use of the Nice classification system, which was not in use in Venezuela for some time between 2008 and 2010. As mentioned above, when analysing the implications for Venezuela with regard the withdrawal from the Andean Community, the use of the national classifier became one of the challenges when applicants sought trademark registrations. Two years post-withdrawal, SAPI enacted an official notice informing the public on the change in classifiers, enforcing from that moment onwards the national one, which is not compatible with the Nice classification system. Venezuela in its attempts to adapt

Asunción, 5 August 1995, and Harmonisation Protocol of norms on Industrial Design, Dec. No.016/1998, signed in Rio de Janeiro, 10 December 1998

⁸⁰⁵ Rondón de Sansó, H., *La Situación Actual de la Propiedad*, at 180

⁸⁰⁶ Romero Méndez, C., *La Entrada de Venezuela en el Mercosur: Repercusiones Interna* (Ildis ed.: Caracas, 2007) at 15 <www.ildis.org.ve/website/p_index.php?ids=7&tipo=P&vermas=99> accessed 4 March 2012

⁸⁰⁷ See Harmonization Protocol of Norms on Intellectual Property matters or trademark ... find article

⁸⁰⁸ Henriquez, L., 'Venezuela al mager de las normas de Propiedad Intelectual del MERCOSUR' (October 2008) 26 *VenEconomía* 1

⁸⁰⁹ Venezuela became a full MERCOSUR member country on 31 July 2012. See Declaración sobre la Incorporación de la República Bolivariana de Venezuela al MERCOSUR, (19 June 2012) <www.mercosur.int/innovaportal/file/4501/1/vzl.pdf> accessed 30 June 2012

Also See Adhesión de la República Bolicariana de Venezuela, MERCOSUL/CMC/DEC. N° 27/12 (30 July 2012)

national legislation to MERCOSUR requirements in 2010 via another official notice, reinstated the use of the international classifier, and yet there are unsolved issues relating to trademark, denomination of source and appellations of origin protection under the current legal framework.⁸¹⁰

Without analysing in depth the Venezuelan trademark system, by pointing out some differences between the Andean Community regime and the one currently in force, it may perhaps be possible to show the challenges involved when seeking intellectual property protection under the regime settled by the national IP Law from 1955. On this note, in Articles 138 and 139 of Decision 486, among the requirements was the indication or statement of which category/class the product or service belonged to. Thereafter, the filing of a single application was to be made indicating to which class, under the international classification system, the trademark was to be registered while at the same time indicating the equivalents within the national classifier.⁸¹¹

As indicated above, in practice, if an applicant's claim sought protection for a trademark covering the products within class 5 (Pharmaceutical and veterinary preparations, etc.) of the Nice Classification system, but according to the Venezuelan Classifier fell under classes 6, 10 and 46, then these were to be only mentioned; therefore filing only a single claim independently of the amount of national classes covering the product. In contrast, IP Law from 1955 clearly states in Article 73 the need to file one claim per class covering the product. In other words, if a trademark that under the Nice Classification system is also covered by several classes within the national one, then a separate application should be filed per national classes affecting the product's trademark.⁸¹²

Furthermore, SAPI's official notice dated 1 October 2010 introduces a new set of requirements when claiming trademark protection. For instance, they reinstated international classification system while demanding the need to indicate its equivalent within the national one, which as highlighted by practitioners increases both the expense and time needed to register determined trademarks.⁸¹³ Besides requiring this double classification, SAPI increases the requirements by demanding that the applicants enclose in the application phonetic, graphic or a search of figurative and phonetic elements depending on the trademark.⁸¹⁴ The patent and trademark office based these new set of requirements on the national framework ruling over the matter, given that Article 71 (g) from the IP law from 1955, somewhat prohibits similarities between registered and potential trademarks within the same or similar class of product(s) that possibly leads to public confusion.

⁸¹⁰ Cadillo, et al 'Legal Certainty, TRIPS and Venezuela' unpublished

⁸¹¹ See Article 151 from Decision 486 – Andean Community

⁸¹² Article 73 from Ley de Propiedad Industrial de 1955, states that an application can only claim trademark registration for a determined group of products in accord with the official classification.

⁸¹³ Pérez-Irazáble, M., 'Venezuela: Standing on its own: Venezuela re-establishes its national IP system in *IP Value 2010 – Building and enforcing intellectual property value: An international guide for the Board room* (10th, Edition) 76.

⁸¹⁴ SAPI, Aviso Oficial de fecha 10 de octubre de 2010. 6.- Indicar correctamente la clase internacional con su equivalente a la nacional

This duality in classifying trademarks under the current Venezuelan system, as highlighted above, came after committing to join MERCOSUR in an attempt to comply with the intellectual property regime.

Regarding patents, the same official notice provides another set of requirements that should be enclosed with the application, but nothing within the notice extends patentability to those products or procedures previously protected under the Andean Community regime.

On a positive note, it is believed that Mercosur could be a way to increase legal certainty in the region, but so far everything is dependent on each member country's ability to adapt its legislation accordingly.⁸¹⁵

5.8. Public health and Patents

This part of the analysis presents the reader with general features from the Venezuelan health care system and the link with medicines, and thereafter assesses the impact of pharmaceutical patents on access to medicines from a legal perspective. The first part briefly addresses past legislative reforms within the health system. The second part analyses the current health care system in accord with the legislative and constitutional reform from 1999. The third part assesses structural organisation and characteristics of the system, and the fourth part aims to highlight the correlation between the reforms and access to medicines;; therefore, price control policy and the list of essential medicines will be taken into consideration for the analysis.

The Venezuelan health care system has gone through some reforms, which could be summarised for the purpose of this work as “pre- 1999 constitutional reform” and “post-1999 Constitutional reform.” The analysis aims to show the reader, in a general fashion, the most relevant changes, and whether or not the current structure provides access to affordable medicines that could be under patent protection. Hence, identifying the system, its coverage and the national list of essential medications, if any, is affected or deterred by patents and enforcement of intellectual property rights in Venezuela.

By assessing the constitutional approach on public health and access to medicines in both stages, pre and post reform, while at the same time taking into consideration structural and legislative changes, will provide a further insight about the system.

The Venezuelan health system falls under the MNHS category provided by Suarez, given that the three main characteristics of this system are met despite the universal coverage envisaged within the constitutional framework, as will be assessed. In Venezuela, the health system is a mixed system. Therefore, both public and private sectors provide health services. On the one hand, hospitals and outpatient clinics constitute the public sector, and private clinics the other. At a first glance, by just looking at the numbers, this should suffice the demand. However, fast infrastructural deterioration and slow problem solving capability within the system, especially as managing both human and economic resources,

⁸¹⁵ See Rodríguez Yong, C., ‘Providing Legal Certainty in South America: Can MERCOSUR Help? (2010) *Pace International Law Review Online Companion*, at 1

lack of supplies and technology, are some of the issues that have been identified as detrimental for the system, and as such, making it inefficient and insufficient.⁸¹⁶

5.8.1. Public Health in Venezuela: Moving towards universal coverage

As mentioned before, the health system underwent reforms from 1998 onwards, when the Political Constitution was reformed itself. This new approach settled in Article 83 of the constitution and contains both citizens rights and the State's obligation by providing health as a fundamental social right, while at the same time creating an obligation for the State to safeguard it as part of the right to life.⁸¹⁷ The same constitutional provision goes beyond delimitating the concept of health into addressing the extent to which this is to be safeguarded, highlighting the need to prompt and develop policies addressed to giving quality of life, collective well-being and access to health services.

One of the main challenges within the system derives from the high cost bared by the Government, given that many of the first aid health care centres are either not functional or perceived as reliable by patients. Thereafter, hospitals are used instead, for which costs are higher.⁸¹⁸ In 2002 some structural changes were seen within the health system, as a popular health programme had been implemented. This was the "Barrio Adentro y Hospitales del Pueblo" (Inner Slums and Popular Hospitals) that was to cover and take care of those who could not afford private insurance and those not formally employed. The latter point has also been identified as a challenge for the current health system, since it portrays existing inequalities when accessing health care.⁸¹⁹

The aforementioned access inequalities contradict the universal coverage provided by the Constitution within Article 84. To a certain extent the government is creating further health benefits by ensuring that those who cannot afford the costs of illness also have the opportunity to receive treatment. Another thing to take into consideration under the new Constitutional health structure is the fact that free of charge services are to be provided, hence, ensuring the population with access to health care.⁸²⁰ This is particularly important when analysing the patent system and its relation to access to affordable medicines in all of the systems analysed.

Universal Coverage as understood by WHO, aims to ensure everyone's access to the needed health services and promotes preventive, curative and rehabilitative procedures that should also be of sufficient quality and effectiveness while at the

⁸¹⁶ Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?', in Jaén, M., Salvato, S., Daza, A., and Rivas, J., *Costo de la Salud en Venezuela: Gasto y Sostenibilidad Financiera del Sistema de Salud* (IEASA eds. Caracas, 2006) at 30-31

⁸¹⁷ Article 83 from the Constitución Bolivariana de la República de Venezuela, 1999

⁸¹⁸ Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?' at 31

⁸¹⁹ *Ibid* at 35.

⁸²⁰ Article 86 from the Constitución de la República Bolivariana de Venezuela, 1999. See Also *Ibid* at 35.

same time safeguarding users from financial hardship.⁸²¹ But to ensure universal coverage, a good or efficient financing system should also be implemented. In this regard, the Venezuelan Constitution within Article 86, not only self imposes the duty to create a Social Insurance health care system based on universal coverage, but also financial hardship should not be faced by individuals making use of the system given the solidarity principle embedded within it. In other words, allocating sufficient funding to the health system and administering it relies exclusively on the Government as provided by the Constitution and special laws.⁸²²

Furthermore, the special law regulating Venezuela's health system is Ley Orgánica de Salud (Health Organic Law – hereinafter LOS), that governs over every aspect related to health within the national territory extended, but not limited to, determining structure, function, financing and controlling health care service delivery.⁸²³ Nevertheless, it is important to highlight that LOS is from 1998 and the universality principle found within the Constitution dates from 1999. Although it is known that a legislative project is being discussed at the National Assembly, until this date (2012) this law has not been formally abrogated nor reformed.

So far, Venezuela's health challenge is actually providing everyone -independently of their level of contribution, if at all- with proper universal coverage, which shall be financed with Governmental funds, tax payers and citizens' contributions.⁸²⁴

5.8.2. General Structure

The Venezuelan health system, as described above, has structurally changed about four times; the last reform's implementation is still incomplete, as LOS continues to be discussed at the National Assembly.

Accordingly, the national system can be, in a general fashion, structured into two subsystems: the public and the private mainly. This classification seems to correlate with each type of institution's means of funding or financial sources. Public institutions are, mainly, those founded with taxpayers money and mandatory contributions; and the private ones, are the ones funded by private sources.⁸²⁵

A few entities are part of this public sector: namely Ministerio del Poder Popular para la Salud (Ministry of Health –hereinafter MPPS) that was created or renamed in June 2009 via Decreto N° 6.732, published in Gaceta Oficial de la

⁸²¹ See further, The World Health Report: Health Financing Systems - The Path to Universal Coverage, WHO, (Geneva – 2010) at. ix. And Sustainable Health Financing -Universal Coverage- Universal Coverage, and Social Health Insurance, WHO, Fifty Eight World Health Assembly Resolution WHA58. 33, (Geneva-16-25 May 2005)

⁸²² Article 86 from the Constitución de la República Bolivariana de Venezuela, 1999

⁸²³ Article 1, Ley Orgánica de Salud, Gaceta Oficial N° 5.263 Extraordinario del 17 de septiembre de 1998, Re printed G/O N° 36.579 de fecha 11/11/1998

⁸²⁴ Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?' at 40

⁸²⁵ González R, M., 'Reformas del sistema de salud en Venezuela (1987-1999): balance y perspectivas' in Serie 111 Financiamiento del desarrollo, Naciones Unidas – CEPAL (Santiago de Chile, 2001) at 9

República Bolivariana de Venezuela N° 39.202 dated 17/JUN/09. This Presidential Decree reorganised the entire Public Administration's functions and organisation, hence its name Decreto sobre la Organización y Funcionamiento de la Administración Pública Nacional - Decree about functions and organization of the National Public Administration. The same Decree in Article 17 settles MPPS's competences, accordingly, to which this entity governs the national health system designing and delimitating national health programmes, surveying food and medicine production among other important competences.⁸²⁶

Designing and implementing policies related to national production of medicines, supplies and biological products are one of MPPS's competences that were established within Article 17(7) from this law. This is of particular importance given that the Ministry of Commerce should also take part when drawing up such policies.

The Ministry of Health's internal structure is provided, or was provided, by a prior Decree in 2006 when this was Ministerio de Salud instead of Ministerio del Poder Popular para la Salud. Decree N° 5.077 of 22 December 2006 and also published within Gaceta Oficial N° 38.591 from 26 December 2006 contains the Ministry's Organic Regulation. This Regulation establishes not only the internal structure but also delimits functions. On the one hand, the ministry is the main body governing the national health care system, but on the other it also has attached entities responsible for providing health services within the public sector.

Among the most important entities are: the Instituto Venezolano de los Seguros Sociales – Social Insurances Venezuelan Institute (hereinafter IVSS); the Instituto Nacional de Higiene Rafael Rangel – Rafael Rangel National Health Institute (Hereinafter INH); Instituto de Previsión y Asistencia Social del Ministerio de Educación – Institute for Prevention and Social Assistance from de Ministry of Education (Hereinafter IPSAME), and the Instituto de Previsión Social de las Fuerzas Armadas – Armed Forces Social Prevention Institute (hereinafter IPSFA), among others.

IVSS has particular importance, given its tripartite source of founding and the fact that pensions and other social security benefits from most workers in Venezuela are managed by this entity.⁸²⁷

In relation to medicines, INH is rather important, since this is the Institute taking care of prevention, observance and health control, including pharmaceuticals produced and/or distributed within the country.⁸²⁸ Independent of the entity, if it is related to health it may be attached to both the Ministry of Health and/or another ministry such as i.e. the labour one. Therefore, it is possible to find employees covered by two different institutions, creating inequities when accessing health care.⁸²⁹

⁸²⁶ See Article 17 from Decreto N° 6.732, published in Gaceta Oficial de la República Bolivariana de Venezuela Gaceta N° 39.202 dated 17/JUN/09

<intranet.inapymi.gob.ve/Formatos/Gaceta_39202.pdf> accessed 10 June 2012

⁸²⁷ <www.ivss.gov.ve> accessed 14 September 2013

⁸²⁸ <www.inhrr.gob.ve/instituto/instituto.html> accessed 14 September 2013

⁸²⁹ Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?' at 35

5.8.3. Main Characteristics

Given the fragmented structure within the system, the main characteristics⁸³⁰ can be summarised as various sources of financing, such as: the State, insurances, employees and individuals.

There are no homogenous provisions of services within the system. Some only provide ambulatory services, whereas others like the hospitals managed by the Ministry of Health and IVSS provide not only ambulatory services but also treatment and rehabilitation or follow up. The system per se is complex, and there is a lack of information for the users. There are visible inequities to access public health care, since not only does misinformation about the system exist, but also a person needs to be either employed or belong to the formal working market, or in the case of not being employed, working in determined professions so as to entitle them to a certain kind of coverage.

The system's fragmentation also deters real possibilities for bulk procurement that eventually challenges large-scale purchase of medicines. Bulk procurement and purchase on a large scale of medicines – essential medicines, is one of the suggestions given by WHO to tackle barriers to access and affordability. This issue will be developed further within the following heading. Real per capita expenditure on health details seems to be impossible to get, accordingly to scholars who attempted to analyse financial and health expenditure in Venezuela. In 2000, WHO highlighted Venezuela's expenditure per capita as the lowest within the Latin-American region, expending an average of \$ 298, whereas countries like Chile and Brazil spent \$581 to \$428 respectively.⁸³¹

5.8.4. Health Services and Coverage

Health services and access to medicines are provided within LOS and the Ley Orgánica del Sistema de Seguridad Social – Social Security Organic Law (hereinafter LOSS); the latter one published and ultimately reformed in Gaceta Oficial No 39912 and dated 30 April 2012. Given the Constitutional mandate in safeguarding health through social health care, there are a few interesting things that arise.

As described within the pre-Constitutional Reform in 1999 heading, the health system underwent four important reforms that regardless of purpose never became fully implemented. However, in the process of providing universal coverage, in all three legislative bodies (the 1999 Constitutional text, LOS from 1998 and the latest LOSS reform from 2012) “catastrophic or high cost illnesses”

⁸³⁰ The characteristics of the system were mainly take from the readings: Jaén, M., et al., *Costo de la Salud en Venezuela: Gasto y Sostenibilidad Financiera del Sistema de Salud* (IEASA eds. Caracas, 2006) at 1-201; González R, M., ‘Reformas del sistema de salud en Venezuela (1987-1999): balance y perspectivas’ in Serie 111 Financiamiento del desarrollo, Naciones Unidas – CEPAL (Santiago de Chile, 2001) 1-39; Organización Panamericana de la Salud, ‘Perfil del sistema de servicios de salud de la República Bolivariana de Venezuela’ Programa de Organización y Gestión de Sistemas y Servicios de Salud (2a. Ed. 14 de Mayo 2001) at i-20

⁸³¹ González R, M., ‘Reformas del sistema de salud en Venezuela (1987-1999): balance y perspectivas’ in Serie 111 Financiamiento del desarrollo, Naciones Unidas – CEPAL (Santiago de Chile, 2001) at

are brought to the spotlight as an especial category. On the one hand, the Constitution foresees protection from financial hardship through shaping social policies with the Government itself as the main guarantor,⁸³² and on the other hand, the previous reform foresaw a public health subsystem that defined or delimited the extent of these catastrophic illnesses.

Despite chronological issues, both LOS and new LOSS seem consistent. One in mandating to create clinical and epidemiological research, programmes for prevention and treatment of chronic illnesses, while at the same time allocating funding for prevention and treatment of catastrophic or high-cost illnesses for patients with low or no financial means.⁸³³ And the other one specifically provides integral attention for catastrophic illnesses.⁸³⁴

When analysing the legislation and structure in light of these provisions, access to affordable medicines to treat catastrophic, chronic and/or high cost illnesses seem to be part of the Government's duties within safeguarding and guaranteeing health care. Therefore, delimitating which are these illnesses, the medication in itself and where and how to find it are questions that should also be found within both legislative frameworks and health system provisions. Instead, the information regarding these illnesses is briefly found on the IVSS website.⁸³⁵

In light of LOSS Article 18, social benefits are delimited, and among those treatment for catastrophic illnesses. Therefore, it is within this institution's – IVSS- functions or duties to provide medicines for patients afflicted by any of the 13 illnesses enumerated by IVSS.⁸³⁶ Namely cancer, multiple sclerosis, hepatitis,

⁸³² Article 86 from Constitución de la República Bolivariana de Venezuela. "Toda persona tiene **derecho a la seguridad social como servicio público de carácter no lucrativo, que garantice la salud y asegure protección** en contingencias de maternidad, paternidad, enfermedades, invalidez, **enfermedades catastróficas**, discapacidad, necesidades especiales, riesgos laborales, pérdida de empleo, desempleo, vejez, viudedad, orfandad, vivienda, cargas derivadas de la vida familiar y cualquier otra circunstancia de previsión social. El Estado tiene la obligación de asegurar la efectividad de este derecho, creando un sistema de seguridad social universal, integral, de financiamiento solidario, unitario, eficiente y participativo, de contribuciones directas o indirectas."

⁸³³ Article 56(3) and (4) Ley Orgánica de Salud, Gaceta oficial N° 5.263 Extraordinario del 17 de septiembre de 1998, Re impresa en Gaceta Oficial N° 36.579 dated 11 de noviembre de 1998 (hereinafter LOSS)

⁸³⁴ Article 18 from LOSS

⁸³⁵ See Ley que Regula el Subsystema de Salud, Gaceta Oficial N° 5.568 Extraordinario de fecha 21 de Diciembre de 2001. This law highlighted the former Labour and Health Ministry's competences, among which Article 9 (4) and (15) points out both the need to write medical protocols defining which illnesses are to be protected/covered, and the need for the President to delimitate the budget and allocation of funding to finance the Fondo Especial a la Atención de Enfermedades de Alto Costo, Riesgo y Largo Plazo – Especial Fund for High-Cost, Risk and long term illnesses. This legislation became abrogated via legislative reform in Gaceta Oficial N° 37600 dated 30 December 2002

⁸³⁶ *Idid*. Thus far, finding any official regulation/statement or presidential Decree or even medical guides other than those briefly stated at IVSS website, establishing what is considered a catastrophic illness or high cost within the Venezuelan context has not been possible. Therefore, and after a phone consultation with the Centro Venezolano para la Clasificación de Enfermedades – CEVEDE, it can be assumed that Venezuela follows suggestions and guidelines by both WHO and PAHO

rheumatoid arthritis, hematologic, transplants, attention deficit hyperactivity disorder, osteoporosis, schizophrenia, pulmonary hypertension and chronic kidney disease in the terminal phase are the assumed to be high cost illnesses covered by Venezuelan social security system. The website highlights that other diseases are also considered as catastrophic, but no information whatsoever is found within the aforementioned legal framework or website.

Previously in Venezuela a Health Subsystem used to define via Protocols those illnesses covered by social security, whereas nowadays besides the enumeration available on the IVSS website and the seven health programmes (Tuberculosis, Immunisations, Cardiovascular diseases, Diabetes, HIV/AIDS, PNANNA – National Programme for Children’s Medical Attention, and Breastfeeding) conducted by the Health Ministry –MPPS, there is no further information on these medical guides for the rest of the diseases highlighted above. Strikingly, only the Tuberculosis programme contains or publicly displays a medical protocol⁸³⁷ to treat the illness.

Despite enumerating those illnesses, the Asociación Venezolana de Alegría, Asma e Inmunología seems to be lobbying for inclusion of other respiratory illnesses, such as asthma, which reportedly afflicts twenty per cent (20%) of Venezuelan children between the ages 6-7 years old and sixteen per cent (16%) between the ages 13-14 years old. More or less one in five children is afflicted by this chronic respiratory illness.⁸³⁸ WHO recognised asthma as a chronic respiratory disease,⁸³⁹ hence, should not this be also considered and treated by IVSS? After all, Venezuela follows both WHO and PAHO suggestions as mentioned earlier. Nevertheless, before understanding the connection between the Venezuelan health system and access to medicines, essential medicines and patents within the IVSS and MPPS context, it is important to remember that IVSS does not only provide health care services, but also takes care of peoples’ pensions.

The mixed management sought reforms for both fields simultaneously, which has been criticised as one rationale behind failing to successfully either reform or implement the system’s reforms in the past.⁸⁴⁰ One of the lessons from past reforms is the fact that health reforms should and could be different from the ones attempted in the pension system, and given the structural challenges realistic and feasible policy definition is needed.⁸⁴¹ The same scholar in his report for CEPAL suggested a couple of interesting points - in case of future reforms - of which some seem to have been taken into consideration by the legislator in 2008 and 2012.

⁸³⁷ See Directrices para el Despistaje, Diagnóstico y Tratamiento de la Tuberculosis en Pacientes con Indicación de Terapias Biológicas, MPPS, <www.mpps.gob.ve/index.php?option=com_content&view=article&id=915&Itemid=946> accessed 15 June 2012

⁸³⁸ Sociedad Venezolana de Alergia, Asma e Inmunología, ‘En Venezuela: uno de cada cinco niños sufre de asma’, <www.svaai.org.ve/noticias/informacion-para-pacientes/35-noticias/95-en-venezuela-uno-de-cada-cinco-ninos-sufre-de-asma.html> accessed 15 June 2012

⁸³⁹ *Asthma*, World Health Organization, Fact Sheet N° 307 (May 2011)

<www.who.int/mediacentre/factsheets/fs307/en/index.html> accessed 15 June 2012

⁸⁴⁰ González R, M., ‘Reformas del sistema de salud en Venezuela (1987-1999)’ at 29

⁸⁴¹ Ibid González at 31

In this regard, the modifications in 2008, besides practically rewriting the law, whilst health benefits were delimited, brought about some inconsistencies. Given this doctoral thesis focuses on patents and access to medicines, only those suggestions – reform related to medicines and health care provisions – will be taken into consideration, despite the fact that further financial and organisational reforms are deemed relevant for a health system's effective performance. Reforming the whole health system, in accord with Gonzalez, goes beyond health per se, as the system's sustainability is fundamental for a full and successful implementation.

Given the existing and diverse health care needs, Gonzalez considers it rather important to combine actions addressed to tackle both infectious and nutritional illnesses, and chronic or catastrophic illnesses, since in Venezuela both epidemiologic patterns coexist and demand innovative and efficient health care attention. One priority sector relates to children's nutrition, immunisation and attention in general for pregnant women; the second health priority regards the treatment and prevention of both cancer and cardiovascular illnesses; and the third aspect concerns HIV/AIDS.⁸⁴²

As highlighted above, Venezuela is epidemiologically diverse and therefore medical attention within the health care system has been divided into three levels within LOS. This legislation in Article 28 addresses the need to delimitate each medical centre's capabilities according to the patient treatment needs.⁸⁴³ Thereafter, the first two levels of medical attention are given in out-patient clinics where promoting health, preventing illnesses, diagnosing and treating these differs as the first level takes everyone without discrimination, whilst the second has criteria to take in patients based on age, sex, illness and requirements.⁸⁴⁴ The third level of medical attention handles specialised cases, or in other words, only patients with determined needs –chronic illnesses– with/without hospitalisation.⁸⁴⁵

LOS as it is today does not provide further information, but a report in 2001 by PAHO indicates a deeper classification within the levels of attention than originally established by law. In this regard, there is a division between out-patient clinics for rural and urban areas; the first ones provide medical attention in places with a population lower than 10,000 habitants and these are destined to give primary health care without hospitalisation, whereas in the second ones, even when hospitalisation is not provided, specialized medical care is.⁸⁴⁶ Furthermore, the second level of medical attention is only provided in establishment for hospitalisation where the three levels of medical attention can be given.⁸⁴⁷ This report follows the classification given by the health subsystem found in Gaceta Oficial N° 32.650 from January 1983 that became abrogated by the legislative reform in 2002.

⁸⁴² Ibid González at 33

⁸⁴³ See Article 28 Ley Orgánica de Salud, Gaceta oficial N° 5.263 Extraordinario del 17 de septiembre de 1998, Re impresa en Gaceta Oficial N° 36.579 dated 11 de noviembre de 1998

⁸⁴⁴ Ibid Articles 29 and 30 from LOSS

⁸⁴⁵ Ibid Article 31 from LOSS

⁸⁴⁶ Organización Panamericana de la Salud, 'Perfil del sistema de servicios de salud de la República Bolivariana de Venezuela' Resumen Ejecutivo, Programa de Organización y Gestión de Sistemas y Servicios de Salud (2a. Edition, 14 de Mayo 2001) at 11

⁸⁴⁷ Ibid at 12

Having in mind the classification in LOS, and the fact that the subsystem was abrogated, finding an up-to-date health care structure seems rather challenging. It has been highlighted, that the latest LOSS reform does not address the issue and the LOS enforced today is from 1998 and thus portrays significant delays that at the same time may contradict constitutional principles.⁸⁴⁸ Assuming the validity of LOS, health care attention is provided on three levels; mainly hospitals and outpatient clinics within the public sector. However, in 2002 with the Inside Neighbourhood Programme, a set of popular clinics began operating providing specialised and good quality medical attention mainly destined to take patients from marginalised rural areas of the country.⁸⁴⁹ Summing up, this programme represents the first level of attention, and according to reports, solves up to 80% of health problems, followed by popular medical practices, popular clinics and the people's hospitals.⁸⁵⁰

5.8.5. Access to Medicines

The former health subsystem law in Article 9 (4) and (15) pointed out both the need to write medical protocols defining which illnesses are to be protected/covered, and the need for the President to delimitate the budget and allocation of funding to finance the Fondo Especial a la Atención de Enfermedades de Alto Costo, Rison y Largo Plaza – Especial Fund for High-Cost, Risk and Long Term Illnesses. But since this legislation became abrogated via legislative reform in Gaceta Oficial N° 37600 dated 30 December 2002, it is not clear whether these protocols are written or not and if so where they can be found.

Thus far, the only protocol available as such on MPPS's page is the one to treat Tuberculosis, which includes the medicines or active compounds used.⁸⁵¹ Two things are to be highlighted from the protocol: one, the active compounds listed on there are also to be found on the Venezuelan List of Essential Medicines, and secondly it is not clear whether or not tuberculosis is considered either a high cost or a chronic illness.

MPPS bylaw structures the Ministry in Article 2, assigning functions and competences to Ministers and Vice Ministers offices. Among those, the Vice Ministry Office for Collective Health, and the Vice Ministry Office for Health Recourses are identified as the ones in charge of both creating health programmes and coordinating the purchase and distribution of medical supplies. At the same time, each Vice Minister's office is structured into several Divisions. Among these, the Health Programme Division has the duty to coordinate with the Supply Division from the Vice Ministers Office for Health Resources to define

⁸⁴⁸ González, M., 'Políticas de Salud en Venezuela: Ni lo urgente, ni lo importante' (2005) 18 *Anales Venezolanos de Nutrición*, at 39-44

⁸⁴⁹ Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?' at 31

⁸⁵⁰ Ojeda Liendo, J., 'Barrio Adentro, una Política Pública de Salud Emergente de Atención' Revista FACES (Universidad de Carabobo, 2007) <servicio.bc.uc.edu.ve/faces/revista/a15n26/15-26-7.pdf> accessed 10 May 2012

⁸⁵¹ See Directrices para el Despistaje, Diagnóstico y Tratamiento de la Tuberculosis en Pacientes con Indicación de Terapias Biológicas, MPPS, <www.mpps.gob.ve/index.php?option=com_content&view=article&id=915&Itemid=946> accessed 15 June 2012

medical supply policies to ensure people's access to health.⁸⁵² Another important Division to take into consideration is the General Division for Medical Supply Production; this one should encourage both the public and private sectors to produce medical supplies –medicines– in accordance with the Public National Health System's priorities.⁸⁵³ The General Division for Medical Supply Distribution is also rather important for access to essential medicines; therefore, its functions will be described within the heading below that analyses access to essential medicines.

The legislation's wording suggests a division between chronic⁸⁵⁴ and high-cost illnesses,⁸⁵⁵ but reference is only made to treatment of catastrophic diseases. Although none of these are defined within the current legislation, WHO through its regional office –PAHO– comes close to a definition by pointing out the seriousness of the medical conditions associated with the high costs in terms of both drug therapies and health care services necessary to treat the patient, demanding significant financial resources on behalf of those affected.⁸⁵⁶ If high costs are associated with catastrophic illnesses due to their consequences on those affected, then a chronic illness can also entail fatal consequences not only associated with the disease per se, but also expenses incurred by the affected ones.⁸⁵⁷

Given the new principles –free access, quality, universality, and solidarity– embedded within the new health reform had made the Government readdress health policies towards pharmaceutical availability, rational use and accessibility by drawing up the national health policy.⁸⁵⁸ Part of this, are the new missions or social initiatives⁸⁵⁹ to solve or pay social debts,⁸⁶⁰ as highlighted by scholars, including free access to pharmaceuticals and/or reduced price.

⁸⁵² See Article 29(9) from Reglamento Orgánica del Ministerio de Salud, published in Gaceta Oficial N° 38.591 del 26 de diciembre de 2006 (hereinafter Reglamento MINSALUD)

⁸⁵³ See Article 33(2) from Reglamento MINSALUD

⁸⁵⁴ According to the WHO, chronic diseases are those of long duration and generally slow progression, such as cardiovascular diseases, cancer, diabetes and respiratory illnesses among others. See WHO, Health Topics, Chronic Diseases <www.who.int/topics/chronic_diseases/en/> accessed 20 June 2012

⁸⁵⁵ Chronic diseases are generally treated with high cost medicines, therefore, a chronic disease could also be understood as a high cost illness derived from overwhelming expenditure on healthcare and medicines. See 'Access to High-Cost Medicines' *infra* note 313. See also, *Preventing chronic diseases: a vital investment*, WHO global report, World Health Organization (Geneva, 2005) at 66

⁸⁵⁶ *Access to High-Cost Medicines in the Americas: Situation Challenges and Perspectives*, Technical Series N° 1 Essential Medicines, Access, and Innovation, Panamerican Health Organisation (September 2010) at 10

⁸⁵⁷ This can be inferred from various readings on the WHO and PAHO site addressing the severity of these illnesses. See *Ibid* at 34

⁸⁵⁸ Organización Panamericana de la Salud, 'Perfil del sistema de servicios de salud de la República Bolivariana de Venezuela' Resumen Ejecutivo, Programa de Organización y Gestión de Sistemas y Servicios de Salud (2nd Ed, 14 May 2001.) at 7

⁸⁵⁹ Definition given by the Ministerio Popular para la Cultura – Ministry of Culture – in its own website

<www.misioncultura.gob.ve/index.php?option=com_weblinks&view=category&id=5&Itemid=4> accessed 10 June 2012

5.8.6. The Essential List of Medicines in Venezuela

Previous to the aforementioned health reform, the national list of essential medicines or *Formulario Terapéutico Nacional* – National Therapeutic Formulary- was and is put together by the Ministry of Health in cooperation with national universities,⁸⁶¹ despite the changing name of this Ministry. In this respect, *Ley de Medicamentos* –Medicines Law (hereinafter LAMED)- contains certain aspects that shall be taken into consideration to elaborate the National Therapeutic Formulary.

In the light of LAMED, essential medicines are those destined to satisfy Venezuelans' population health care needs⁸⁶² that may vary from country to country. Therefore, the same legislative framework provides that WHO and PAHO guidelines are to be taken into consideration when classifying medicines as essential, and therefore, includes them within the National Therapeutic Formulary.⁸⁶³ Furthermore, access to medicines in Venezuela seems to be safeguarded and provided by several stakeholders within the public and some times even by the private sector. In this regard, the creation of *Comate Nacional Terapéutico* – National Therapeutic Committee- is foreseen in the legislation with the purpose to revise the aforementioned list, among other functions.⁸⁶⁴ Another important body seems to be the *Consejo Nacional del Medicamento* - National Medicines Council- created to advice the president on related matters.⁸⁶⁵

Among the Ministry of Health's competences, are creation and implementation of pharmaceutical policies to ensure safety, availability and access to essential medicines found on the National Therapeutic Formulary. In addition, others are ensuring that medicines are safe, efficient, of good quality and affordable.⁸⁶⁶ Hence, the Ministry of Health bylaws in Article 38 recognises *Servicio Autónomo de Elaboraciones Farmacéuticas* –Autonomous Service of Pharmaceutical Elaborations (hereinafter SEFAR) as part of its own structure.⁸⁶⁷ SEFAR is an important entity attached to MPPS, since this one ensures accessibility, availability and rational use of essential medicines via policies addressed to incentivise national production of medicines.⁸⁶⁸ Besides producing this entity, it

⁸⁶⁰ Alvarado, C., *et al.* 'Cambio Social y Política de Salud en Venezuela' Sección Especial: Reformas Progresistas en Salud (Mayo, 2008) 3 *Medicina Social* 2, 113-129, at 119-120

⁸⁶¹ Previously known as Ministerio de Salud y Desarrollo Social and currently known as the Ministerio del Poder Popular para la Salud. *See also* 'Perfil del sistema de servicios de salud de la República Bolivariana de Venezuela'

⁸⁶² Article 7 *Ley del Medicamento*, published in *Gaceta Oficial* N° 37.006 dated 3 agosto 2000

⁸⁶³ *Ibid*

⁸⁶⁴ Article 11 from *Ley de Medicamentos*, *Gaceta Oficial* N° 37.006, and *Resolución* N° 247 published in *Gaceta Oficial* N° 37.453 dated 29 May 2002

⁸⁶⁵ *Ibid* Article 16 and 17

⁸⁶⁶ Article 17 (25) from *Decreto* N° 6.732, sobre Organización y Funcionamiento de Administración Pública Nacional, publicado en *Gaceta Oficial* de la Republica Bolivariana de Venezuela N° 39.202 de dated 17 June 2009

⁸⁶⁷ Article 38 from *Decreto* N° 5.077 dated 22 December 2006, published in *Gaceta Oficial* N° 38.591 del 26 de diciembre de 2006

⁸⁶⁸ SEFAR was created by *Decreto* N° 3.061 dated 8 July 1993, published in *Gaceta Oficial* N° 35.263 dated 29 July 1993, *Reformado Parcialmente* y publicado en *Gaceta Oficial* N° 4.949 Extraordinario de fecha 10 de agosto de 1995. *See*, SEFAR, 'Objectives'

<www.sefar.gob.ve/index.php/sefar/quienes-somos> accessed 10 June 2012

aims also to strengthen the observance of pharmaceuticals, which is mainly carried out by the INHRR's authorisation to commercialise.

Studies have shown that up to 2001, only 2% of the population had access to essential medicines, therefore, a programme named SUMED subsidises up to 80% of the price of medicines included on the list and those prescribed by public health care providers.⁸⁶⁹ Further reports suggest as an achievement of the current health system the fact that an average of 106 different medicines had been provided for free to *Barrio Adentro* users.⁸⁷⁰ Allegedly, this year alone, SEFAR-SUMED donated around 175,000 pharmaceutical products,⁸⁷¹ and SEFAR gave to a single Estate – Bolivar Estate- more than 400,000 products between pharmaceutical and medical supplies for Estado Bolivar to use in its missions'.⁸⁷²

In 2000, the national list of essential medicines contained around 280 active ingredients, and in 2003, given money control policies, a list of medicines receiving preferential currency was published via *Gaceta Oficial*.⁸⁷³ Despite having foreign and national pharmaceutical companies in Venezuela with manufacturing capabilities, most raw materials are imported into the country, and therefore, these companies need to apply for foreign currency purchase authorisations from CADIVI.⁸⁷⁴

Currently around 1,200 active compounds are part of this national list of essential medicines, and in accord with IVSS high functionaries, 119 pathologies are protected in Venezuela for which free access to medicines is guaranteed by this institution's "high cost pharmacies."⁸⁷⁵ Reportedly, free medicines are given at IVSS pharmacies to patients afflicted with illnesses such as cancer, diabetes among other high cost-chronic diseases, as a result from billions of bolivars (national currency) invested by the current government into these health programmes.⁸⁷⁶ However, an extract number of treated illnesses, and medicines

⁸⁶⁹ Organización Panamericana de la Salud, 'Perfil del sistema de servicios de salud de la República Bolivariana de Venezuela' Resumen Ejecutivo, Programa de Organización y Gestión de Sistemas y Servicios de Salud (2nd. Ed, 14 May 2001.) at 7

⁸⁷⁰ Alvarado, C., *et al.* 'Cambio Social y Política de Salud en Venezuela' at 120

⁸⁷¹ See, Ministerio del Poder Polular para la Cultura, 'Sefar Sumed donó alrededor de 175.000 unidades en medicamentos e insumos' (Caracas, 4 April 2012)

<www.casadelartista.gob.ve/index.php?option=com_content&view=article&id=90:sefar-sumed-dono-alrededor-de-175000-unidades-en-medicamentos-e-insumos&catid=4:noticias-fca&Itemid=1> accessed 10 June 2012

⁸⁷² See, Ministerio del Poder Popular para la Salud, 'Más de 400 mil rubros médicos entregó Sefar en Bolívar', (Caracas, 22 May 2012)

<www.mpps.gob.ve/index.php?option=com_content&view=article&id=1459:mas-de-400-mil-rubros-medicos-entrego-sefar-en-bolivar&catid=1:ultimas-noticias&Itemid=18> accessed 10 June 2012

⁸⁷³ See Resolución 283, publicada en *Gaceta Oficial* N° 328.307 dated 14 April 2003

⁸⁷⁴ Explicar CADIVI, see Also, Nicole Yaupur, 'La falta de divisas enferma a la industria farmacéutica, el universal (2 de Mayo de 2012)

⁸⁷⁵ IVSS blog de Administración, 'Más de 885 millones de BSF invirtió el IVSS en enfermedades de Alto Costo'

<www.ivss.gob.ve/MÁS%20DE%20885%20MILLONES%20DE%20BSF%20INVIRTIÓ%20IVSS%20EN%20ENFERMEDADES%20DE%20ALTO%20COSTO> accessed 15 June 2012

⁸⁷⁶ Oswaldo González Moreno, 'Garantizados medicamentos para enfermedades de "alto-costo"' Prensa Asamblea Nacional:

provided for free at these pharmacies are not available. It must be remembered that IVSS provides health care services to those affiliated, one way or another, to this institution via employment of some sort. Therefore, it is interesting to spot an initial inequality when accessing medicines in Venezuela. As suggested within the introductory chapter, pharmaceutical patents are considered by one side of the literature as detrimental to the access of medicines, however, by analysing public health care policies other factors seem to play an important role in both ensuring and denying access to medicines.

5.9. Access to Affordable Medicines in Venezuela: Price Control Policy

Within the previous paragraph a brief assessment was made of the existence in Venezuela of a 'national list of essential medicines' and that some of these are provided for free at determined pharmacies. Given the disparities within Venezuelans' purchasing capabilities, due to a fragmented social system, Ley de Medicamentos foresees in Article 12 the State's possibility in regulating medicine prices as to ensure fair access to those with low economic resources.⁸⁷⁷

This regulation is known as price control policy, and the Venezuelan Government has made use of it throughout the years to ensure peoples' access to most needed medication, or at least tried to do so. Official statements in 2005 regulated approximately 135 active ingredients found in nearly 1,142 essential medicines, therefore, providing more affordable medicines to an estimated 75% of the illnesses protected in Venezuela.⁸⁷⁸ The same press release indicated the availability of a list containing medicines and its prices; however, the prices indicated in such a report are "referential prices" and not "maximum prices". This led the government to emphasise during 2012 the need to use the "maximum price for customer purchase – precio máximo de venta al público" instead of the referential price, so as to ensure the affordability of medicines.⁸⁷⁹ The latest press release came after the Ley de Costos y Precios Justos – Fair Costs and Prices Law, hereinafter LCPJ- was enacted in July 2011 after creating Superintendencia de Costos y Precios Justos – Fair Costs and Prices Superintendence, hereinafter SUNDECOP - .

However, in 2003 via Gaceta Oficial N° 5.684, around 1105 medicines were price regulated by the Government, and the list also indicated the maximum sales price for consumers.⁸⁸⁰ The use of this "maximum sales price" is later on foreseen by LCPJ in Article 31(7) that describes SUNDECOP's attributions. Interestingly, on

<www.asambleanacional.gob.ve/index.php?option=com_content&view=article&id=35792%3Agarantizados-medicamentos-para-enfermedades-de-alto-costo&catid=1%3Alatest-news&Itemid=246&lang=es> accessed 15 June 2012

⁸⁷⁷ Article 12, Párrafo único from Ley de Medicamentos, Gaceta Oficial N° 37.006, dated 3 August 2000.

⁸⁷⁸ Prensa MSDS y Prensa RNV, 'Regulado precios de 1.142 medicamentos esenciales'

<www.rnv.gov.ve/noticias/?act=ST&f=&t=24517> accessed 15 June 2012

⁸⁷⁹ Últimas Noticias, 'Fijación de Precios Justos a Medicamentos refuerzan su carácter social', 3 July 2012 <www.sundecop.gob.ve/index.php?option=com_content&view=article&id=300:fijacion-de-precios-justos-a-medicamentos-refuerzan-su-caracter-social&catid=49:ultimas-noticias&Itemid=18> accessed 5 July 2012

⁸⁸⁰ See Gaceta Oficial N° 5.684 date December 2003

the list regulating medicines' prices, not only active ingredients are found, but brand medicines as well.⁸⁸¹

On the one hand, prices are regulated, but on the other regulated medicines seemed to have disappeared from pharmacies' shelves, and even brand name medications are reportedly hard to find nationwide.⁸⁸² Other sets of challenges are also taking a toll on the availability of medicines in Venezuela. Allegedly, by increasing the tax unit, administrative proceedings relating to imports, registrations and authorisations to commercialise also became more expensive for pharmaceutical companies to supply the Venezuelan market.⁸⁸³ Price control policies seem to influence market entry of new or products already available elsewhere.⁸⁸⁴ This, together with the identified challenges above, could be the reason behind pharmacies' shelves being empty. Regarding active ingredients and generic versions of patented medicines, both SEFAR and Ley de Medicamentos settle promotion, prescription, and production of generics found on the national list of essential medicines by public health care providers so as to ensure peoples' access to medicines.

In previous years, Venezuela took part in joint negotiations with four other Andean countries to purchase antimalarics, managing to reduce medicine prices by between 36% and 90% of the estimated average price within the Andean sub-region.⁸⁸⁵ Accordingly, several Latin American countries also participated in other joint purchases ventures, and therefore, ensuring access to medicines. There is not only a national health policy, but also a medicine policy for the Andean sub region that includes joint purchases as part of the initiatives that deal with access to affordable and good quality essential medicines.⁸⁸⁶

5.9.1. Medicine Policy for the Andean Sub region: Further Efforts to Achieve Access to Medicines regardless of Patents

The above mentioned health policy's achievements are handled under the Andean Health Organization which is at the same time part of the Andean Integration System. Even though confusing, Venezuela still belongs to this organisation

⁸⁸¹ See Annex containing the list and own highlights denoting regulation of both brand medicines, and active ingredients

⁸⁸² Casanova, R., 'Medicinas en Crisis', *El Universal*, 12 May 2012

<www.eluniversal.com/opinion/120511/medicamentos-en-crisis> accessed 15 June 2012

See also Primera, M., 'Venezuela extiende el control Estatal de precios', *El País*, 23 November 2011

<internacional.elpais.com/internacional/2011/11/23/actualidad/1322083666_953043.html> accessed 17 June 2012

⁸⁸³ Códio Venezuela, 'Escases de medicamentos por control de precios', *Últimas Noticias*, 29 February 2012

<www.codigovenezuela.com/2012/02/noticias/pais/escasez-de-medicamentos-por-control-de-precios> accessed 17 June 2012

⁸⁸⁴ Lanjouw, J., 'Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry', *NBER Working Paper Series*, Working Paper 11321 (2005) at 22

⁸⁸⁵ *Los Medicamentos Esenciales en la Región de las Américas: logros, dificultades y retos*, Organización Panamericana de la Salud, Centro de Documentación OPS/OMS en el Perú – Catalogación en la fuente (2007) at 16

⁸⁸⁶ See, *Política de Medicamentos de la Subregión Andina*, Organización Mundial de la Salud, WHO/DAP/97.3 (1993).

despite having withdrawn from CAN. In 1970, under the auspice of the Government of Peru and its Ministry of Health, the Andean Health Organization was created with the aim of tackling health needs within the region.⁸⁸⁷ Later on in 1971, the Hipólito Unanue Cooperation Agreement was subscribed to by all six original Andean Community member states (Bolivia, Colombia, Chile, Ecuador, Peru and Venezuela). This Agreement foresaw a series of measures or actions as highlighted by the legal instrument, designed to solve health challenges and also to reach a certain level of norm harmonisation.⁸⁸⁸ Despite having subscribed to the aforementioned agreement, this organisation did not become an integral part of the Andean Liberalisation Programme until 1998 when Decision 528 formally gave it a higher status within the organisation.⁸⁸⁹ As highlighted previously, Venezuela has taken part in several initiatives to address purchasing drugs for malaria and AIDS/HIV.⁸⁹⁰ Allegedly, countries located within the Andean Sub-region continued working together towards the same goal – to improve peoples' health conditions.⁸⁹¹

However, it is not clear what the terms are for Venezuela's membership once withdrawing from the Andean Community; other than Venezuela remaining part of the Liberalisation Programmes, such as the Hipólito Unanue. On the one hand, with regard to the Agreement and the following Agreement on Attachment Terms from the Hipólito Unanue Agreement, Venezuela takes the Andean Community framework as the one governing this Organisation, but on the other hand nothing is clearly stated in case of a member State withdrawing from the Andean Community. Admittedly, this agreement also needs to be denounced, as for withdrawal purposes, but what happens once this becomes an integral part of the AC. Countries like Chile, in dispute settlement cases, agree to taking the Andean Court of Justice as the jurisdictional body to solve conflicts arising with other member states. However, this is something that needs to be agreed upon well beforehand.⁸⁹² So the question is, whether Venezuela needs to renegotiate its membership terms now that it no longer belongs to the Andean Community.

This Andean body is of a certain importance for Venezuela given the initiatives on tackling the needs regarding medicines within the country, especially for the public sector's distribution of free medicines. In 2008, a report named

⁸⁸⁷ Organismo de Salud Andino Convenio Hipólito Unanue, Historia, <www.orasconhu.org/quienes-somos/historia> accessed 20 July 2012

⁸⁸⁸ Article 3 from Convenio "Hipólito Unanue" sobre Cooperación en Salud de los Países del Área Andina.

⁸⁸⁹ See Decisión 528 Designación del Convenio Hipólito Unanue sobre Cooperación en Salud de los Países del Área Andina como "Organismo Andino de Salud - Convenio Hipólito Unanue", and Decisión 445 del Consejo de Ministros de Relaciones Exteriores, se aprobó la adscripción del Convenio Hipólito Unanue al Sistema Andino de Integración <www.comunidadandina.org/Documentos.aspx#> accessed 20 August 2012

⁸⁹⁰ Organismo Andino de Salud Convenio Hipólito Unanue, "Un ejemplo de Integración Exitosa: Diez Países Latinoamericanos y un Propósito en Común por las Personas que Viven con Sida/VIH" (Lima – Perú, 2003) 1-47

⁸⁹¹ This remark relates to Chile working closely in this cooperation regardless of its associate member state status in the Andean Community. Other countries, such as Brasil, Argentina, Paraguay and Uruguay have also taken part in some of the initiative to buy massive amounts of medicines to supply AIDS/HIV patients' needs.

⁸⁹² Article 3, Proyecto de Decisión "Términos de la Adscripción al Sistema Andino de Integración y Reglamento de Organización y Funciones del convenio Hipólito Unanue" (1998)

Observatorio de Precios de Medicamentos Escenciales de la Subregión Andina, prepared for the Andean Health Organization, highlighted that the Venezuelan private health sector did not actually implement or take into consideration public health policies to purchase or acquire medicines, as this sector has its own information system.⁸⁹³ As highlighted above, relevant reduction of prices was achieved in the past, benefiting the public health care sector that delivers free medication in accord with national regulation. Despite the Government having identified illnesses afflicting the Venezuelan population, ensuring universal access to medicines is another topic.

5.9.2. Venezuela and the Doha Declaration on Public Health

When addressing public health, reference to the Doha Declaration and TRIPS needs to be made. Venezuela, as a WTO Member, supported several communications and motions before the Council for Trade-Related Aspects of Intellectual Property aiming to raise awareness over public health issues, and implications on pharmaceutical patent protection.⁸⁹⁴ An active roll seemed to have taken place as to have a Doha Declaration better suited with the needs of developing and least-developed nations.

In this respect, Venezuela, jointly with a number of WTO Members, in 2001 lobbied for public health emergencies to be defined by each country member instead of having a universal definition. In addition, it lobbied for the Declaration to include a clause stating that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health.⁸⁹⁵ Both suggestions are found within the Doha Declaration adopted on 14 November 2001.⁸⁹⁶

Similar efforts were drawn following the aforementioned Declaration, by another group lobbying -Venezuela included- for the solutions envisaged in Paragraph 6 of the Doha Declaration not to be limited exclusively to determined categories of countries, given that any Member could face difficulties in making use of compulsory licences.⁸⁹⁷

Later on, the General Council in Decision WT/L/540 from 1 September 2003 complemented the previous Declaration by amending Paragraph 6 according to the suggestions made by all the countries lobbying for them. Interestingly

⁸⁹³ Villacorta Santamato, J.. 'Observatorio de Precios de Medicamentos Escenciales para la Subregión Andina' Organismo Andino de Salud – Convenio Hipólito Unanue (May, 2008) at 21

⁸⁹⁴ See the list of documents involving Venezuela before the DOHA Declaration from September 2003. <commerce.nic.in/wto_sub/trips/trips_index.htm> accessed 10 August 2012

⁸⁹⁵ Communication from the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/296 (29 July 2001)

⁸⁹⁶ Declaration on the TRIPS Agreement and Public Health, World Trade Organization, WTO/MIN(01)/DEC/2 (20 November 2001)

⁸⁹⁷ Communication from Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, 'Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health' IP/C/W/355 (24 June 2002)

enough, the deadline to accept the TRIPS amendment has been extended,⁸⁹⁸ but Venezuela is yet to accept the amendment before the WTO.

As a WTO Member, Venezuela has at its disposal the use of flexibilities found in the TRIPS Agreement, but to make use of them most likely this needs to be re – implemented given its current legislative jump in the past with the IP Law from 1955. On the one hand, every country is entitled to take measurements to protect public health, but on the other hand, by just making use of bulk procurement and initiatives like the ones from the Hipólito Unanue Agreement might not suffice the country's needs, and international commitments. In this regard, the Andean Sub-region has recognised the value embedded in protecting intellectual property rights as a way to promote innovation within the pharmaceutical field, while at the same time a balance must be found between public health and IPRs to ensure people's access to medicines.⁸⁹⁹

Thus, representative's from the Cámara Venezolana del Medicamento – Venezuelan Medicines Chamber (Hereinafter CAVEME), has pointed out that legally protecting inventions is also part of public policies addressed to promote scientific development and also economical growth, benefiting general or specific sectors such as public health.⁹⁰⁰

Nevertheless, a few years after, Venezuela took part in these negotiations at the WTO to achieve better understating about the flexibilities and also lobbied to reach TRIPS amendments, and in 2007 the Government considered patents for pharmaceutical products as being restrictive for access to medicines since this protection raises the price of medicine.⁹⁰¹ Even though 6-10%⁹⁰² of medicines available in the market are patented, thus proving difficult to assert in a general fashion that patents deter access to medicines or essential medicines, the government still deems patents as one of the main factors strengthening the pharmaceutical industry's monopoly.

Public declarations from high ranking officials against the patent system also seem to be contradictory. On the one hand, patent protection is pointed put as some kind of failed system in promoting innovation and R&D of medicines mainly because patents create monopolies, but on the other hand, and in the

⁸⁹⁸ WTO Members will have until 31 December 2013 to accept the TRIPS Amendment. See World Trade Organization, 'Amendment of the TRIPS agreement – third extension of the period for the acceptance by Members of the protocol amending the trips agreement', WT/L/829 (5 December 2011)

⁸⁹⁹ Política Andina de Medicamentos. '*Comisión Técnica Subregional para la Política de Acceso a Medicamentos*', Organismo Andino para la Salud – Convenio Hipólito Unanue (Lima –Perú, 2009) 1-36 at 21

⁹⁰⁰ Allende, F., 'Las Patentes de Invención y la Salud Pública', in Antequera Parilli, R., and Andrade, R., (eds.) Congreso Internacional de Propiedad Intelectual: Derecho de Autor y Propiedad Industrial – Homenaje al Dr. Ricardo Antequera Parilli, (Universidad de Margarita, 2004) Tomo 1, 5-463, at 182

⁹⁰¹ Sáman, E., 'Patentes y Salud Pública', *Aporrea*, 30 September 2007<www.aporrea.org/tecnologia/a41884.html> accessed 25 August 2012

⁹⁰² Allende, F., 'Las Patentes de Invención y la Salud Pública', at 186

same report, high costs derived from obtaining patent protection make it difficult for small pharmaceutical companies to sell their products at a lower cost.⁹⁰³

Later on in 2008, another statement was made public in relation to SAPI's Official Notice disregarding the Andean IPR framework, but this time even when it was not directly due to minimum standards of protection that Venezuela withdrew, indirectly patent protection for pharmaceuticals is blamed for a lack of R&D on diseases afflicting poor countries, such as Dengue.⁹⁰⁴

Interestingly enough, in the Andean Medicines Policy from 2009 that prioritises the diseases in need for effective medication, each country is highlighted among the strategies to promote R&D in a specific place. Therefore, this also makes use of those suggestions given in the Strategy and Plan of Action for Public Health, Innovation and Intellectual Property.⁹⁰⁵ Evidently, this also requires a certain solidarity on behalf of the pharmaceutical industry, but ultimately, creating incentives to promote R&D on the most needed medication in a determined country is left to the Governments to delimitate.

5.9.3. Marketing approvals

Before a pharmaceutical product reaches either hospitals or pharmacies there are a few necessary steps to follow, which can differ from country to country. Within the Venezuelan context, pharmaceutical products need to obtain mandatory authorisation to commercialise from the national health institute Instituto de Higiene Rafael Rangel, as national laws and international treaties regulate these. The national laws are Ley de Medicamentos - Medicines Law (L Med), Reglamento de la Ley del Ejercicio de la Farmacia - Regulation of the Law of Pharmacy Practice (hereinafter Pharmacy bylaw), and Normas de la Junta Revisora de Productos Farmaceuticos del Instituto de Higiene Rafael Rangel - Standards from the Rafael Rangel Hygiene Institute's Pharmaceutical Products Review Board (hereinafter Review Board Standards). The only international treaty or agreement ruling over the matter is the TRIPS Agreement, given that Venezuela withdrew from both the Andean Community of Nations (Decision 486), and also denounced in 2006 the Free Trade Agreement between Colombia, Mexico and Venezuela known as the 3G Agreement.⁹⁰⁶ Therefore, the former two treaties are no longer applicable to Venezuela.

Despite intellectual property rights being of a private nature, given their social purpose and specifically pharmaceutical products, they require Governmental

⁹⁰³ Samán, E., 'Patentes y Salud Pública'

⁹⁰⁴ Frente de Trabajadores Socialistas MPPILCO-SAPI, 'Venezuela: Revolución Bolivariana, Patentes y Acceso a Medicamentos', Aporrea, 26 September 2008.
<www.aporrea.org/tecno/a64530.html> accessed 20 August 2012

⁹⁰⁵ Política Andina de Medicamentos. 'Comisión Técnica Subregional para la Política de Acceso a Medicamentos', at 29-31

⁹⁰⁶ See Status of the Free Trade Agreement Colombia, Mexico, and Venezuela
<www.sice.oas.org/trade/go3/g3indice.asp#PropInt> accessed 20 August 2012

approval which is not limited to patent rights, but also extends to the quality and safety verification procedure.⁹⁰⁷

So as to comply with safety and quality procedures, a product must obtain marketing approval from the National Health Institute.⁹⁰⁸ This was created in 1938, initially, to backup the Health Ministry's projects, but later on became the place of reference on Venezuelans' health by surveying and controlling the safety and quality of those products and services related to health.⁹⁰⁹

Both L Med and the Pharmaceutical Practice bylaws require pharmaceutical products to be registered and approved by the National Health Institute. Article 18 from L Med not only defines the Sanitary Permit as the procedure followed by a pharmaceutical product to obtain marketing approval, but also states that every medicine, regardless of the place where it was produced, needs to obtain such a certificate before it can even be produced or distributed within the national territory.⁹¹⁰

The national law provides a broad definition for medicines and also one for generics,⁹¹¹ but does not give the same treatment to pharmaceutical products, since it only states what is considered as a pharmaceutical product.⁹¹² In contrast, the Pharmacy bylaw provides a concrete definition for "pharmaceutical products."⁹¹³ Other important issues addressed within the national law are: which are products requiring registration, which is the authority providing registration certificates,⁹¹⁴ delimits the scope of clinical trials necessary to obtain registration certificate,⁹¹⁵ and requests the creation of a special body within the National Health Institute to draft a set of internal rules with the criteria to follow when examining an application to obtain marketing approval.⁹¹⁶ The Pharmaceutical bylaw provides specific set of rules delimitating the issues defined by L Med. For instance, Article 53 divides pharmaceutical products into two classes.⁹¹⁷ First, into *known products* –productos conocidos- which are those containing one or many active ingredients previously registered in Venezuela, and second, into *new products* –productos nuevos- defined as those constituted by one or many active

⁹⁰⁷ Astudillo Gómez, F., *La Protección Legal de las Invenciones: Especial referencia a la Biotecnología*, (2nd Ed., Universidad Gran Mariscal de Ayacucho, 2004) at 288

⁹⁰⁸ Article 19 from Ley de Medicamentos, published in Gaceta Oficial N° 37.006 from 3 August 2000

⁹⁰⁹ Instituto de Higiene Rafael Rangel, 'Información General', and Gaceta Oficial N° 19.700 from 18 October 1938 < www.inhrr.gob.ve/instituto/instituto.html > accessed 25 August 2012

⁹¹⁰ Supra Article 18, Ley de Medicamentos

⁹¹¹ Article 3 and 8, Ley de Medicamentos

⁹¹² See Article 5, Ley de Medicamento

⁹¹³ Article 51 from Reglamento de la Ley del Ejercicio de la Farmacia, published in Gaceta Oficial N° 4.582 dated 21st May 1993

⁹¹⁴ Articles 19 and 33 from Ley de Medicamentos

⁹¹⁵ Articles 70 – 73 from Ley de Medicamentos

⁹¹⁶ Articles 33 – 34 from Ley de Medicamentos. This set of internal rules are Normas Generales de la Junta Revisora del Instituto de Higiene "Rafael Rangel"

<www.caveme.org/asuntos.aspx?i=3&s=42> accessed 10 September 2012

and Norma Venezolana de Biodisponibilidad y Bioequivalencia, published in Gaceta Oficial N° 38.499 dated 14 August 2006

⁹¹⁷ Article 53 from Reglamento de la Ley del Ejercicio de la Farmacia, published in Gaceta Oficial N° 4.582 dated 21st May 1993

ingredients that have not been registered previously in Venezuela. This classification is important at the moment when applying for the marketing approval, since a set of different requirements applies to each class.

Among the main functions of the Board of Review, the most important ones are evaluating scientific and analytic documents supporting the approval of pharmaceutical products, and also surveying and controlling those products commercialised in the national territory.⁹¹⁸ Both competences constitute administrative procedures that will lead to either approving or rejecting an application for the interested party. Scholar Francisco Astudillo raises an important question regarding legitimacy to claim marketing approvals, since the public administration cannot grant such a certificate to an illegitimate third party, and within the legal framework there is nothing linking the Patent Office with the National Health Institute: so how can the Board of Review know who is and who is not a legitimate third party?⁹¹⁹ In his opinion, this could only happen if there is a certain collaboration between the stakeholders involved, but thus far no linkage provisions are available within the national framework.

Even when L Med rules over everything related to medicines, and also provides the general framework, the Pharmacy bylaw is the one giving more precise information on the requirements and definitions. In this respect, Article 55 from the bylaw needs to be read in conjunction with Capítulo II, Grupo E and Grupo G –Chapter II, Group E and Group G- in order to submit all the legal requirements to obtain a marketing approval. As of 2006, bioequivalence and biodisponibility studies are mandatory in accord with the Norma Venezolana de Bio Equivalencias y Bio disponibilidad. In previous years, these studies were not required since the National Health Institute had pending the approval of these guidelines.⁹²⁰

Following the aforementioned provision, pre-clinical and clinical trials are required for new products, but known products are not required to submit full pre-clinical and clinical trials.⁹²¹ The legislation, as Valentín points out, not only contains a typing error but also waives these trials for known products since a summary with the most relevant data will suffice and substitute a full pre and clinical trial.⁹²² The problem with this, is that the data to be provided can only be obtained if the file is consulted by a third party, which technically leads to disclosing information that is to be protected against unfair competition.⁹²³ Previously, when the Free Trade Agreement between Colombia, Mexico and Venezuela was in force, Venezuela had the obligation to protect undisclosed information for 5 years, unless the third party interested in obtaining approval to commercialise similar products had express authorisation from the original party.⁹²⁴

⁹¹⁸ See Capítulo I, Grupo A, 1 – 3 from Normas de la Junta Revisora del Instituto de Higiene “Rafael Rangel” from 1998.

⁹¹⁹ Astudillo Gómez, F., *La Protección Legal de las Invenciones*, at 289

⁹²⁰ González, J., ‘La Protección de la Información Regulatoria y los Procedimientos para Autorizaciones de Comercialización de Productor Farmacéuticos en Venezuela’, (UCAB-CAVEME, 2006) 1-33, at 17

⁹²¹ Capítulo II, Grupo E from Normas de la junta Revisora

⁹²² González, J., ‘La Protección de la Información Regulatoria’ at 17

⁹²³ Ibid at 18-21, See also Article 39 (3) TRIPS Agreement.

⁹²⁴ See Article 18-22 from Acuerdo de Libre Comercio Colombia, México Venezuela (3G)

In the Andean Community context, Decision 632 from 7 April 2006, left it to each country to regulate the length of the exclusivity period for the protection of undisclosed information.⁹²⁵ This Decision came after a polemic court ruling from the Andean Court of Justice ordered Colombia to modify its internal law on the basis of the Andean IP framework which did not foresee the protection of undisclosed information for any specific length of time, therefore giving the court 90 days to void the national Decree protection of this kind of information for 5 years (as required by the FTA Colombia-United States).⁹²⁶

Initially, Decision 486 did not foresee anything different than TRIPS.⁹²⁷ In other words, no exclusive or specific period of time was required to protect undisclosed information, but later on with Colombia and Peru signing FTA with the United States of America, these were deemed to protect undisclosed information for a period of between 5 to 10 years, depending on the product.⁹²⁸ Venezuela argued the validity and sustainability of the Andean Community after it legislated in 'favour' of member countries implementing higher standards of protection, allegedly the pharmaceutical linkage generally foreseen within the FTA's frameworks was another reason behind Venezuela's rationale to withdraw from the ACN.

5.10. Competition Law and Pharmaceutical Patents in Venezuela

In general terms, patents are seen as a natural monopoly granted by the State to reward the inventor for his contribution to society. Some may not agree completely with this position. The right to exclude another for a determined period of time is nothing else but a competition law exception, and therefore, it is not right to conceive patent rights as monopolies in the strict sense of the word.⁹²⁹ Other scholars suggest that given the nature of patents, there is a tension between the rights granted under intellectual property law and the rights protected under competition law. Thus, creating economical barriers for products' market entry is a challenging topic, since excluding others from competing with similar products –in the case of medicines– at the same time seems highly difficult.⁹³⁰

Before addressing some common factors between competition law and IP in Venezuela, and trends when dealing with patent infringements within the

⁹²⁵ Croplife Latin America, 'Países Andinos: En libertad para proteger datos de Prueba', Temas, Edición N° 58 (Mayo 2006)
<www.croplifela.org/pages_html/pdfs/Temas58_Decision_andina_proteccion_datos.pdf>
accessed 30 August 2012

⁹²⁶ International Centre for Trade and Sustainable Development, 'Venezuela se retiraría de la CAN', Puente Quincenal, Volume 3, Número 8 (Mayo 2006)
<ictsd.org/i/news/puentesquincenal/10314/> accessed 30 August 2012

⁹²⁷ Article 266, Decision 486 – Andean Community
<www.comunidadandina.org/ingles/normativa/D486e.htm>

⁹²⁸ Article 16.10 from Free Trade Agreement Colombia-United States of America.
< www.tlc.gov.co/publicaciones.php?id=727> accessed 30 August 2012

⁹²⁹ Supra Allende, F., 'Las Patentes de Invención y la Salud Pública', at 184

⁹³⁰ Mogollón Rojas, I., 'Propiedad Intelectual & Derecho de la Competencia Económica' in *Propiedad Intelectual: Temas Escogidos* (Hermanos Vadell Eds. Caracas-Venezuela, 1997) at 34-37

pharmaceutical field, it is important to establish Venezuela's competition law regulatory framework.

In 1992, via Official Gazette N° 34.880 dated 13 January 1992, was enacted Ley para Promover y Proteger el Ejercicio de la Libre Competencia – PROCOMPETENCIA Law. And it was this legislation that also created the official body responsible for surveying, controlling, regulating and solving any issue related to competition law. Article 19 creates the Superintendencia para la Promoción y Protección de la Libre Competencia - Superintendence for Free Competition also known as PROCOMPETENCIA, which is a body attached to the Ministry of Commerce.⁹³¹

Despite looking after ensuring free competition, there are certain practices that are illegal in the first place; there are few exceptions or legitimate economic restrictive practices, such as patents, where infringement would actually be considered unfair competition.⁹³² Nevertheless, PROCOMPETENCIA Law is also intended to protect these rights from unfair competition. The legislation starts with general prohibitions, followed by especial ones (Articles 6-16), and continues with unfair competition practices as the accessory part of the legislation.⁹³³ Thereafter, a precise definition of what is to be understood for these practices is not obtained via legislation.

Thus, the 'unfair competition' concept is an interesting link between competition law and IP. On the one hand, the legislation in Article 17 provides the intention to eliminate the competitor as a key element embedded within unfair competition. Therefore, the following are the main ways portraying unfair competition: false or deceiving publicity to prevent or limit free competition;⁹³⁴ promoting goods and services based on false advantages; disadvantages and/or risks derived from the competitor's product;⁹³⁵ and commercial bribery, infringing industrial secrets and simulating products⁹³⁶. But on the other hand, in general terms, the doctrine and jurisprudence understand a third party's dishonest and reprehensible behaviour towards another merchant as unfair competition.⁹³⁷

Precisely this general behaviour has been also interpreted within Venezuelan doctrine 'as making use of other's effort to obtain certain benefits'. This is an argument frequently seen in unfair competition claims related to marketing approvals obtained by third parties.

Accordingly, marketing approvals are obtained from the National Health Institute, whose Board of Review analyses every certificate's application before the product itself can be commercialised nationally. However, as described above, *known products* only forego a summarised procedure which excludes clinical trial. Allegedly, undisclosed information is used by third parties submitting

⁹³¹ Article 19 - 29 from Ley para promover y Proteger la Libre Competencia, Gaceta Oficial N° 34.880 from 13th January 1992

⁹³² Morles Hernández, A., *Curso de Derecho Mercantil: Introducción a la empresa y al empresario*, UCAB eds. Tomo I (Caracas-Venezuela, 2004) 3-763, at 448

⁹³³ Ibid at 481

⁹³⁴ Article 17 (1) Ley Procompetencia

⁹³⁵ Article 17 (2) Ley Procompetencia

⁹³⁶ Article 17 (3) Ley Procompetencia

⁹³⁷ Supra, Morles Hernández, A., 'Curso de Derecho Mercantil', at 456

marketing approval application for generic versions, hence, making use of the originator's efforts by supporting their product with data that was already given to the Board of Review.

The aforementioned assumption leads the discussion to the relation between undisclosed information and trade or industrial secrets in Venezuela. As argued before, both Decision 486 and Article 39 (1) from TRIPS deemed every member country responsible for ensuring protection of undisclosed information against unfair practices. But Article 260 – Decision 486 also regards industrial secrets as undisclosed information within the control of an individual or legal person that may be used for productive, industrial or commercial activities and that is capable of being transmitted to a third party as long as it has commercial value because the information may be related to the nature, purpose and characteristics of the product⁹³⁸ – pharmaceutical products and undisclosed information.

Infringing on the protection of industrial secrets– as undisclosed information– is precisely the closest link between competition law and intellectual property law, given that not only are individual rights protected, but also the unfair practice can be sanctioned if in the light of competition law both reprehensible behaviour is proven and the relevant market is affected.⁹³⁹

Some scholars have also briefly pointed out the link between intellectual property and competition law in Venezuela, by asserting that a third party seeking to obtain marketing approvals for *known products* is partaking in the reprehensible behaviour of abusing the efforts of others, which is considered unfair competition as described by both doctrine and jurisprudence.⁹⁴⁰

PROCOMPETENCIA has been very clear in verifying the concurrence of elements when ruling over third parties' marketing approvals as unfair competition. In Resolution No SPPLC/0016-2003 the court considered the intention to eliminate a competitor via unfair competition practices as a key factor. The case related to infringements over industrial secrets, since allegedly the third party used undisclosed information to apply for marketing approval without informing the originator about it. There are two important things settled by the court in that decision: firstly, it highlights that the abbreviated procedure for *known products* does not necessarily imply infringements over industrial secrets since a third party only needs to choose on the application form whether the application is for *new products* or *known products*, and by choosing the second option the company is neither accessing a private file nor making use of the efforts of others. Secondly, the court addresses the elements necessary to fulfil Article 17 from Ley PROCOMPETENCIA, indicating the *bad faith* is also embedded within unfair competition practices.⁹⁴¹

⁹³⁸ Article 260 (b) Andean Decision 486

⁹³⁹ Díaz Canada, H., 'La Competencia Desleal relacionada con los Derechos de Propiedad Intelectual' in Antequera Parilli, R. and Andrade, R., (eds.) *Congreso Internacional de Propiedad Intelectual: Derecho de Autor y Propiedad Industrial – Homenaje al Dr. Ricardo Antequera Parilli*, (Universidad de Margarita, 2004) Tomo 1, 5-463, at 356

⁹⁴⁰ González, J., 'La Protección de la Información Regulatoria' at 25

⁹⁴¹ Aventis Pharma vs Farma, S.A., Despacho del Superintendente, Superintendencia para Promoción y Protección de la Libre Competencia, dated 23 de Julio de 2003, Resolución No SPPLC/0016-2003

During 2003, four resolutions dealt with unfair competition due to alleged infringements over industrial secrets. One way or another the court kept on ratifying the need to verify *bad faith* as an element incurred in commercial practices, and by complying with legislative requirements a company or third party cannot be deemed as an infringer.⁹⁴² Therefore, proving unfair competition due to misappropriation of undisclosed information, seems rather challenging.

Another interesting fact related to competition law, is that patent infringement cases seem to be solved as competition law cases instead. In 2008, Resolution N° SPPLC/ 0018- 2008 dealt with a couple of interesting issues, patent procedure infringement, applicability of Andean Decision 486 and anti-competitive practices. This court case was between Meyer Productos Terapéuticos, S.A. vs Sanofi-Aventis,⁹⁴³ where the latter had obtained in 1998 patent protection for the procedure to manufacture “Procedimiento para la preparación de Enantiómeros Dextrogiros de Alfa-(Tetrahidro-4,5,6,7-Tien (3,2-C) Piridil-5) (Cloro-2-Fenil) Acetado de Metil”⁹⁴⁴ as published in Official Journal N° 377 dated 6 December 1993. Sanofi-Aventis had exclusive rights until 5 February 2008. However, Meyer in 2006 obtained authorisation to commercialise the generic version with the same active ingredient (Clopidogrel Bisulfato).

Meyer sought to compete in the market with two generic versions based on the same active ingredients as the patented version owned by Sanofi-Aventis. Thereafter, when the right holder tried to stop the generic producer, this one argued before PROCOMPETENCIA anti-competitive practices; namely abuse of dominant position, restrictive practices and obstructing market access. With regard to patent rights, the court did not dismiss Sanofi’s legitimate right, but it did not disregard the generic producer’s right to obtain marketing approval for the generic product, since in the court’s view, the procedures to manufacture either of the versions were different. Therefore, no patent infringement could be alleged.

Regarding abuse of dominant position, the Court found Sanofi-Aventis as incurring in anticompetitive practices as framed by Articles 5, 6, 8 and 13 from PROCOMPETENCIA law. And the last issues dealt with by this Court related to Decision 486 to determine patent rights, highlighting its applicability despite Venezuela having withdrawn from the Andean Community.

Competition courts have been used to determine whether obtaining marketing approval for *known products* can or cannot be considered as infringement over industrial secrets due to unfair competition. As analysed within the aforementioned case law, and in accord with national regulations, the fact that a third party uses the abbreviated procedure does not necessarily imply that this had access to administrative files that seem to be for the exclusive access of the National Health Institute’s Board of Review.

⁹⁴² See *Pharmacia vs Farma, S.A.*, Despacho de Superintendente, Super Intendencia para la Promoción y Protección de la Libre Competencia, dated 15 de Octubre de 2003, Resolución No. SPPLC/0024-03

⁹⁴³ *Meyer Productos Terapéuticos, S.A. v. Sanofi – Aventis*, Despacho del Superintendente, Superintendencia para Promoción y Protección de la Libre Competencia, dated 15 October 2008, Resolution N° SPPLC/ 0018-2008

⁹⁴⁴ *Sanofi-Synthelabo*, Patent N° Ro50740, Filing date 5 February 1988, Expiration date 5 February 2008, Official Journal N° 377

5.11. Summarising the Venezuelan context

Prior to addressing the factors or elements deterring access to medicines in Venezuela, it is important to summarise some final remarks within the current legal framework, Andean community framework and the Venezuelan public health care model to thereafter convey with the Venezuela strategy of protection for intellectual property rights while balancing access to medicines.

Venezuela's intellectual property regime is based on the IP Law from 1955 as re-implemented following the withdrawal from the Andean Community of Nations. The current legislation is not in compliance with the TRIPS Agreement, therefore, pharmaceutical patents are no longer protected in Venezuela. This argument has availed patent application rejections since 2008. Within the Official Journal of the Patent Office, in 2009 a total of 200 patents were returned on basis of administrative requirements; of these 65 related to pharmaceutical products and processes, and all of them were later on rejected on legislative grounds.

The Andean Community IP regime did comply with TRIPS and also harmonised the system among the countries belonging to the Agreement. As part of the Andean Community, Venezuela also retained certain privileges and duties, among these applying the legislation enforce for a period of 5 years so as to allow an adequate legislative reform. Venezuela, right after the transitional period expired, re-implemented the old legislation bringing the IP system into chaos.

In terms of public health, admittedly, within the last 14 years significant investments within the health care sector have been registered. However, by the country implementing a new system instead of boosting the existing one, more challenges arose and the situation within the sector also deteriorated.

Misinformation and inequalities characterise public health care in Venezuela. Access to medicines is provided for a limited number of diseases; despite this the Government has taken part in the Andean Sub-regional Group to purchase medicines.

6 IDENTIFYING STRATEGIES

Intellectual property rights and access to medicines have been in the spotlight for some time now; even prior to the TRIPS Agreement the pharmaceutical industry lobbied against the generic industry or at least asserted that generics were of inferior quality to branded name ones.⁹⁴⁵ Nevertheless, the debate intensified after ratifying the TRIPS Agreement given that its implementation seemed to compromise public health policies around the world due to a fear raised in medicines prices. Moreover, all signatory nations were not at the same or even on a similar level of development that would ensure, in principle, an “impact-free” implementation. Significant legal reforms were and still are needed to come into compliance with TRIPS.

Whether patents are granted for pharmaceuticals, or certain medicines are given at low or no cost in determined geographical areas, the problem of balancing these rights –patents and access to medicines– worldwide is far from being achieved. The challenge remains, and both developing and least developed countries struggle to provide patent protection while allowing generic production without infringing patent rights or even providing citizens with top of the line medicines at affordable prices.⁹⁴⁶ Given the extent and the diversity within the discourse, both analysis and discussion have been limited in time and geographical extension. This project is limited to Brazil, Chile and Venezuela by mainly focusing on gathering further understanding upon their view and strategies to address patent legislation and access to medicines in each country. Even after the background of each country had been looked at, the real analysis began within the implementation of TRIPS and onwards.

In this respect, the analysis begins with the overall description of the project, its methodology and research questions. The purpose of the research was to identify the strategies used by Brazil and Chile to balance patents and access to medicines, while assessing whether or not Venezuela could benefit from implementing either of the strategies analysed. To provide the reader with some basic knowledge, several aspects were taken into consideration, thus, the general context introduced the concepts of public health, access to medicines, universal coverage, intellectual property rights and patents. This chapter aims to summarise, on the one hand, the aspects that shaped and emerged while setting the international framework relevant to the analysis, i.e. TRIPS Agreement and the access to medicines discourse. And on the other hand, it aims at presenting the “strategies” or “models of protection” identified following the general framework discussed within the background of the study.

As depicted within the introductory chapter, intellectual property rights and access to medicines had been clashing even before the TRIPS Agreement. In an

⁹⁴⁵ See t’ Hoen, E. *The Global Politics of Pharmaceutical Monopoly Power* (the Netherlands, AMB Publishers, 2009)15-16

⁹⁴⁶ Refer to the Supreme Court of India, *Novartis vs. Union of India & Other* CIVIL APPEAL Nos. 2706-2716 OF 2013. The Supreme Court of India prevented patent evergreening due to a clause within the Indian Patent Act. Although this case was not analysed within the research, it is important to mention its relevance within the international framework as it sets an example for countries aiming to balance patent rights while putting their health needs first.

attempt to balance rights, access to essential medicines is considered to be part of the human right to health. But the analysis of this concept brought to the spotlight interesting points denoting further challenges when balancing rights. For instance, the 'right to health' has different interpretations, globalisation does not always have a positive impact, socioeconomic theories and the definition of 'health' per se pose challenges in themselves for achieving adequate access to health care from the theoretical point of view. Then, from a practical point of view, the need for further funding and commitment on behalf of the States as to adequately implement health care policies that assure access to essential medicines has been highlighted.

Within the diverse human rights, international agreements and conventions, access to medicines per se is not expressly protected, however, the 'human right to the highest attainable standard of health' is.⁹⁴⁷ Allegedly, the several interpretations of this right contributed with the creation of derivate rights according to its scope. Nonetheless, today access to essential medicines is as much part of the human right to the highest attainable standard of health, as is access to health care providers. Having said this, it is important to highlight the fact that all three political constitutions –Brazil, Chile and Venezuela– enshrine protection for fundamental rights and among these is access to health.

The current discourse generally refers to the right of access to medicines, but note, that this does not necessarily imply access to 'essential medicines' or the other factors involved in providing it. Some scholars have challenged the use of the definition of 'health' provided by WHO as the basis for the human right to health since this might "outlaw diseases, the infirmities brought on by aging and even mortality."⁹⁴⁸ In practice, diverse epidemiological scenarios, despite having a globalised world⁹⁴⁹ challenge the possibilities in tackling health care needs. When discussing access to medicines, the concept and goal of providing citizens with universal coverage also comes to the spotlight raising the question on whether or not it is feasible for developing and least-developed countries that are lacking resources to implement adequate health care reforms to achieve this goal.

Whether concepts are not sufficiently defined or countries need to comply with international commitments, the challenge in providing adequate health care seems to be dependent from several aspects that go beyond providing patent protection or not. Namely, public health policies consistent with the country's needs, significant investments in infrastructure and human resources, governmental commitment and continuity, decreasing poverty and improving sanitation and prioritising the attention of specific illnesses among several other factors.⁹⁵⁰ Thus far, the study shows the feasibility in implementing public health

⁹⁴⁷ Schroeder, D., 'Does the Pharmaceutical Sector have a Corresponsability for the human Right to Health?' (2011), 20 *Cambridge Quarterly of Healthcare*, 298-308, at 298

⁹⁴⁸ Evans, T., 'A Human Right to Health?', 198

⁹⁴⁹ Informe de epidemiología de WHO

⁹⁵⁰ UN Millennium Project, *Prescription for Healthy Development: Increasing Access to Medicines*, Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines. (Sterling, Va.: Earthscan, 2005) 29-30. Also see World Bank Group, *Improving Effectiveness and Outcomes for the Poor in Health, Nutrition, and Population: An Evaluation of the World Bank Group Support since 1997*, The World Bank (Washington, D.C. - 2009) 5

policies addressed to tackle health needs while at the same time implementing the TRIPS Agreement in at least two of the countries object to the research.

WHO has not only provided countries with general guidelines about public health and access to essential medicines, but it has also harmonised to a certain extent the most important aspects related to the 'highest attainable standard of health.'⁹⁵¹ Within this referential framework the need to implement an adequate health care system together with solving other needs that directly or indirectly affect health, such as poverty, sanitation, housing, education and financial resources are stressed. Ideally, countries' health care systems would cover all of the diseases while providing access to medication. But if this is not feasible due to each country's particular situation, it may be more efficient to begin by moving forward to achieve access to adequate health care and essential medicines instead of not providing anything at all or even perhaps prioritising the illness or illnesses afflicting the most in the national context. Admittedly, this has been part of the success in Brazil's battle against HIV/AIDS; even though there are several other illnesses afflicting an important sum of the population, the focus on and commitment to developing and implementing health care policies consistent with the aforementioned situation has also been highlighted as being influential to the global development of HIV/AIDS health care provisions elsewhere.⁹⁵²

Common health goals, social conscience and political will⁹⁵³ have proven to be key factors in the fight against epidemics, i.e. HIV/AIDS. Also demonstrating that a clear, straightforward and precise discourse is fundamental for people to understand their rights and governmental duties towards them since the topic in itself is broad enough. As for access to medicines, despite the State being the main actor responsible for ensuring adequate implementation of health policies, both the international community and the pharmaceutical industry play an important role in the realisation of health rights.

The pharmaceutical industry develops and produces drugs and services destined to improve people's quality of life. Given this role, it has been questioned whether the industry has a co-responsibility with the human right to health.⁹⁵⁴ When discussing access to medicines, affordability and availability are fundamental, and as it will be discussed below, high prices are generally associated with pharmaceutical patents and the industry per se. Nevertheless, a certain level of co-responsibility has been determined in terms of costs and innovation.

The pharmaceutical industry heavily relies on patent protection. At least three theories argue in favour of the patent system as a tool to create innovation.⁹⁵⁵ However, the efficacy of the system as an engine to incentivise innovation is under public scrutiny since the pharmaceutical industry has allegedly failed to

⁹⁵¹ World Health Organization, 'How to Develop and Implement a national drug policy' 1-83

⁹⁵² Nunn, A. et al. 'AIDS Treatment in Brazil' 1112,

⁹⁵³ Homedes, N. Et al, 'Improving access to pharmaceuticals in Brazil' 129 Points out how remarkable is the fact that Brazil, despite all of the political changes, has manage to mantian in time the programme to treat HIV/AIDS and that the only changes made where addressed to improve the quality in response to the disease.

⁹⁵⁴ Schroeder, D., 'Does the Pharmaceutical Industry have corresponsability' at 299

⁹⁵⁵ Boulet, P., Garrison, C., and t' Hoen, E., 'Drug Patents Under the Sport Light: Sharing practical knowledge about pharmaceutical patents', *Médecins Sans Frontières* (May 2003) at 8
<apps.who.int/medicinedocs/pdf/s4913e/s4913e.pdf> accessed 20 June 2013

engage in R&D in order to address solving priorities related to health needs in developing and least developed nations. Affordable and top of the line vaccines or medicines destined to cure illnesses afflicting the poor are not widely available, which also challenges the patent system's efficiency.⁹⁵⁶

Admittedly, new products bear the investment costs and the rationale behind pharmaceutical products is to allow the companies to both recoup the investment and to obtain revenues for their invention. The cost of developing a new medicine varies largely; during 2012 the cost is estimated to have ranged from \$1.2billion to as much as \$12 billion, which also seems to take into consideration the cost of failure for the industry since it has been said that for every 10 medicines tested in human trials only one may succeed.⁹⁵⁷

On the one hand, patent protection grants to the inventor -pharmaceutical industry- a period of 20 years to recoup their investment. But on the other hand, these 20 years restrict competition in terms of allowing third parties to freely produce the same medicine without the owner's consent. Therefore, the current R&D model has been analysed by scholars whom asserted that a collaborative open innovation model would allow the pharmaceutical industry to come up with breakthrough medicines, while at the same time lowering costs of R&D.⁹⁵⁸

Within the background of the study, several points were brought into the spotlight in terms of definitions and understanding of the system per se. In this respect it was established that regardless of having a unanimous definition as to what a patent is, it is widely accepted that patents are immaterial rights granted by the State to an inventor to reward him for his invention; that is, as long as the invention complies with patentability requirements, the inventor has a period of 20 years to exclude others from using the invention. Inventions are generally not defined either. Nevertheless, the doctrine has come to understand inventions as solutions to a technical problem that satisfy patentability requirements while at the same time are not excluded by virtue of non-patentable subject matters.⁹⁵⁹

Treaties and Conventions shaping the international legal framework, as we know it today, were also addressed. The Paris Convention and the TRIPS Agreement mark the before and after of the protections of intellectual property rights. The Paris Convention, initially, provided the international framework for the protection of intellectual property rights. However, its mandates are not as detailed and extensive as those found within the TRIPS Agreement. Under the Paris Convention, patents were to be granted to inventions that met patentability requirements, however each country had the prerogative to extend patent protection to pharmaceutical or agricultural products.⁹⁶⁰ Later on, the TRIPS

⁹⁵⁶ Ibid

⁹⁵⁷ Herper, M., 'The Truly Staggering Cost of Inventing New Drugs', Forbes, 12 October 2012, Business 1-2. <www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/> accessed 15 June 2013

⁹⁵⁸ Munos, B., 'Using Open Innovation to Tackle the Dearth of Antibiotics' presentation made at the ReAct conference on 'Collaboration for Innovation - The Urgent Need for New Antibiotics' in Brussels, on May 23, 2011

⁹⁵⁹ Thorley, Q.C., S., Miller, R., Q.C. Burkill, G., et al. (eds.) *Terrel on the Law of Patents* (London, Sweet & Maxwell, 2006) at 20-21

⁹⁶⁰ Article 1 Paris Convention. Also refer to the introductory chapter for more information about the history of patents and the provisions within the Paris convention relevant to patents.

Agreement broadened the scope of protection to all fields of technology, whether product or process, as long as the patentability requirements were also met.⁹⁶¹ In this respect, pharmaceutical patents were no longer a prerogative of the State, but instead a mandate imposed on all member States if these were to integrate into the World Trade Organization in 1994.

Despite having a new set of rules, each country implemented TRIPS according to their own needs, or at least attempted to do so. As has been established before, the approach towards the Agreement has not been all that positive among least-developed and developing countries due to public health concerns. In this respect, Brazil implemented TRIPS in a manner consistent with their needs, thereafter enacting the prior consent requirements for pharmaceutical patent applications. Chile engaged in trade negotiations with developed countries, which required it to implement even higher standards of protection, but at the same time achieving further national growth. Venezuela initially implemented the Agreement via the Andean Community, only to later on withdraw from this organisation and re-implement the old IP Law.

6.1. Identifying strategies or models of protection on a case-by-case basis

The comparative law method can be used in academia to pursue legal reform, analyse different systems and transplant solutions into another system.⁹⁶² Venezuela, like many other countries, followed this tradition in transplanting legislation and institutions, hence, amid legal uncertainty, analysing the intellectual property regime only seems convenient and fruitful. Having said this, the purpose of this analysis is not to transplant institutions, legislation or solutions, but more to tailor a system to fulfil both IP and public health needs in Venezuela. Therefore, the following lines will provide in a nutshell the strategy or model used in each country to protect both IP rights and access to medicines. Detailed descriptions and country profiles have already been carried out within the substantive chapters.

Given the extent of the research and the changing variables, the comparison will be divided into two parts. Firstly, within this section's description of each country's strategy, both IP institutions and legal framework and public health context and legal framework will be assessed. Secondly, the strategy aims at answering the question of how these countries tackled the challenges derived from the Agreement. The following chapter, Conclusions and Suggestions, will present the lessons from Brazil and Chile in terms of IP and Public health. When assessing whether or not Venezuela could learn from Brazil and Chile, both advantages and disadvantages will be discussed with the aim of shedding light on the Venezuelan intellectual property doctrine.

⁹⁶¹ Article 7 TRIPS

⁹⁶² Comparative Law in Latin America, The Oxford Handbook of Comparative Law

6.1.1. Brazilian Strategy or model of protection

The historical and political context in Brazil suggests a long battle against oppression and political abuse. Nevertheless, several elements came together to achieve remarkable progress in terms of public health, specifically the battle against HIV/AIDS. The civil society and activists played an important role in both raising awareness over certain health issues and reaching a political change from dictatorship to democracy.

Both intellectual property rights and access to health (extended to medicines and treatment) find protection within the political constitution. IP provisions, specifically pharmaceutical patents seem to be tightly intertwined with public health concerns. Brazil, a founding member of the Paris Convention, has followed a respectable tradition towards protecting IP rights and also is a key player in terms of public health and the fight against HIV/AIDS. Interestingly, pharmaceutical patents were available in Brazil long before TRIPS, but after 1945 the legislation was amended in a way that these kinds of inventions were no longer protected.⁹⁶³

Brazil was among the first South-American countries to implement TRIPS, and also the one which tailored such an implementation by making use of the flexibilities available within the Agreement, and as such this argument partially frames the Brazilian Strategy or model of protection, as will be explained below.

By the time TRIPS became a mandatory adherence, Brazil had been struggling for some time to tackle the HIV/AIDS epidemic.⁹⁶⁴ Allegedly, the programme destined to provide free access to ARV to treat patients living with the illness was in jeopardy between 1990 and 1995 since there was an insufficient supply of medicines.⁹⁶⁵ Later on in 1996, guidelines to supply medicines to treat the disease were created by the Ministry of Health,⁹⁶⁶ which also implemented the public procurement system to purchase and distribute medicines ensuring an increased level of supply that was not existent in the past.⁹⁶⁷

The timeframe for both increasing internal supply of ARVs, and the coming into force of the IP Code implementing TRIPS –compulsory licensing regime- does

⁹⁶³ Oliveira, M., Costa Chaves, G., and Epsztejn, R., 'Brazilian Intellectual Property Legislation', in *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health*, Jorge A. Z. Bermudez, and Maria Auxiliadora Oliveira (eds.) WHO/PAHO Collaboration Center for Pharmaceutical Policies National School of Public Health Sergio Arouca Oswaldo Cruz Foundation, (Nucleus for Pharmaceutical Policies (NAF)/ENSPSA/FIOCRUZ: Rio de Janeiro-Brasil, 2004) 153-162, at 154 <www.law.fsu.edu/gpc2007/materials/LivroTRIPSEnglish2004.pdf> accessed 10 September 2013

⁹⁶⁴ Nuun, A., *The Politics of AIDS Treatment in Brazil* (Springer Ed. 2009)

⁹⁶⁵ Bermudez, J., Oliveira, M., and Andrade de Oliveira, E., 'Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies', in *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health*, Jorge A. Z. Bermudez, and Maria Auxiliadora Oliveira (eds.) WHO/PAHO Collaboration Center for Pharmaceutical Policies National School of Public Health Sergio Arouca Oswaldo Cruz Foundation, (Nucleus for Pharmaceutical Policies (NAF)/ENSPSA/FIOCRUZ: Rio de Janeiro-Brasil, 2004) 129-150, at 144 <www.law.fsu.edu/gpc2007/materials/LivroTRIPSEnglish2004.pdf> accessed 10 September 2013

⁹⁶⁶ This refers to the creation of the Generic Drugs Law by the Brazilian government

⁹⁶⁷ Bermudez, J. Et al 'Expanding access to Essential Medicines in Brazil' 144

not seem to be a mere coincidence. The challenge, in a nutshell, was/is how to solve the HIV/AIDS health care crisis while at the same time complying with international commitments. On the one hand, the whole IP framework had to be amended in views of both constitutional provisions and the minimum standards of protection. INPI –the patent office- would now have to accept patent claims for pharmaceutical products and processes, examine claims caught up within the pipeline and also observe whether or not these claims met with the social function requirement. On the other hand, the public health care sector was also developing a purchase and distribution system aiming to ensure constant supply of ARVs.

How could the Brazilian government deal with all of these interests and needs at once without perishing on its way? As a country with one of the largest economies in the region, determined bargaining power was also embedded. Therefore, the country moved forward in using this power to not only intimidate other trading partners seeking market entry into the Brazilian market, but also allowed them to have wider decision making powers in terms of policymaking. In other words, policy makers seemed to have had in mind a clear goal, which was to balance rights and to gain something from implementing TRIPS.

IP reforms came in two or three stages, indicating that the government was to a certain extent learning from its weaknesses. The first stage of reforms (during 1996) only included some of the flexibilities and safeguards within the Agreement, namely compulsory licensing, experimental use and limited use of parallel imports.⁹⁶⁸ The second stage of reforms coincides with the time when the government was negotiating with a set of pharmaceutical industries to reduce ARVs prices (during 2001); the negotiating team noticed weaknesses within the current patent system in terms of public health concerns.⁹⁶⁹ Prior to these negotiations, the prior consent mechanism was created (1999), thus involving INAPI to evaluate the impact derived from said pharmaceutical patent claims.

Within the current IP Code (or Patent Act) two important mechanisms exist, namely the prior consent mechanism and the local working requirement, which have been rather controverted issues. For the first one, neither jurisprudence nor literature agree on its legality and if it really breaches the TRIPS Agreement. For instance, several attempts have been made for the courts and comptrollers' office to delimit the attributions of the National Health Institute in examining pharmaceutical patents. Several patents have been denied from patent protection given ANVISA's veto over these patent applications submitted before the Patent Office INPI. Even when the prior consent mechanism was set out so ANVISA would assess the impact that such a claim would have over public health concerns, the scope and limits of this analysis were initially not clear. On the one hand, patent applications where to be examined by INPI (patentability requirements), but on the other, ANVISA also understood or misunderstood the scope of its attributions by examining the same patentability requirements as INPI but in light of public health instead.

Prior Consent is a convoluted topic in Brazil, as it was described within the substantive chapter. A series of case law demonstrated that ANVISA was actually misinterpreting Article 18 from the IP Code, which basically establishes that inventions, contrary to health, shall not receive patent protection. However, this

⁹⁶⁸ Oliveira, M., et al., 'Brazilian Intellectual Property Legislation' at 155

⁹⁶⁹ Ibid at 157

provision is said to have been set out in the context of forbidden substances by the law, and not with the interpretation given by ANVISA. To complicate things further, ANVISA never issued or made public for that matter the criteria used to examine the patent applications sent by INPI. It was not until 2013 that finally this agency published RDC n° 21, which addressed the scope of its analysis. Nonetheless, this resolution does not seem to completely clear out the context of the examination in terms of patentability requirements.

Art. 4° Após recebimento dos pedidos de patente encaminhados pelo INPI, a Anvisa analisará tais pedidos à luz da saúde pública, mediante decisão consubstanciada em parecer técnico emitido pela unidade organizacional competente no âmbito da Agência.

Considera-se que o pedido de patente será contrário à saúde pública quando: I - O produto ou o processo farmacêutico contido no pedido de patente apresentar risco à saúde; ou **II - O pedido de patente de produto ou de processo farmacêutico for de interesse para as políticas de medicamentos ou de assistência farmacêutica no âmbito do SUS e não atender aos requisitos de patenteabilidade e demais critérios estabelecidos pela Lei no. 9.279, de 1996.**⁹⁷⁰

Article 4 points out that after ANVISA receives the patent applications sent by the patent office, the agency will assess them in light of the public health context in a binding decision given by the competent department of the agency to carry out the examination. Until this point, the issue seems to be rather clear, but the article goes further in establishing the cases that ought to be considered as contrary to public health. Part II begins by narrowing the rejection to claims that portray an interest to public health policies in the context of the universal coverage granted by SUS –until here it also seemed rather clear- but then appears the phrase “**e não atender aos requisitos de patenteabilidade e demais critérios estabelecidos pela Lei no. 9.279, de 1996**”. This last part could be translated as: “and that do not fulfil or comply with the patentability requirements established by the IP Code”. Thus, two possibilities emerge when interpreting or attempting to translate this past part of the provision. Either ANVISA will continue to examine patent claims in light of patentability requirements, or this is definitely a personal limitation given by the fact that the doctoral student’s mother tongue is not Portuguese. Unfortunately, only time will clarify the issue.

The compulsory licensing regime was also modified in 2003 under the umbrella of de Decree n° 4.830/2003, which specifically settles the frame for compulsory licences in cases of national emergency and public interest. Initially, products imported into Brazil to supply the internal market had to be patented elsewhere or even in Brazil, but the new reform included a provision allowing Brazil to import from other countries the same product even if this had not received patent protection in that country.⁹⁷¹ Compulsory licences can also be issued due to unfulfilment of the local working requirement, which already had been settled within the IP Code (1996), but nevertheless challenged in light of the Paris Convention. Many considered as illegal the provision and duty to fulfil a local working requirement in a period of 3years from the date the patent was granted. At this point, it seems necessary to remember that Brazil justified the provision with the need to boost their national industry, and also to prevent import

⁹⁷⁰Article 4 from the RDC n° 21- ANVISA

⁹⁷¹ Oliveira, M., et al., ‘Brazilian Intellectual Property Legislation’ at 158

monopolies from pharmaceutical companies and all of these in light of the HIV/AIDS crisis.

Regarding public health policies, Brazil's government and society have advocated for equal access and specially to provide affordable medication. Solving the HIV/AIDS crisis in Brazil has been a central issue when developing both the patent regime and public health policies. In the past compulsory licences have been used as a bargaining or pressure mechanism in negotiations with the pharmaceutical industry to obtain lower prices for medicines. When this failed, Brazil issued a compulsory licence by dropping royalties by about 20% from the price already suggested in negotiations. This compulsory licence was extended until 2015, as highlighted within the substantive Brazilian chapter.

Admittedly, implementing the TRIPS flexibilities requires each country to integrate them into their national system. This is said to portray 'changes in the balance of power amongst the parties involved in the bargaining process.'⁹⁷² This has precisely been one of the strengths of Brazil during the negotiation processes. However, since this implementation carries the threat of using a compulsory licence, Brazil faced strong opposition from trading partners.

In May 2000, the American government complained before WTO demanding to call Brazil for consultation over the provisions contained in their IP Law. In their view, the Brazilian government was in breach of TRIPS Articles 27-28 since Article 68 from the IP Code required patent holders to comply with the local working requirement. Reportedly, the pharmaceutical industry lobbied efficiently enough as for the WTO to establish a panel before the Dispute Settlement Body from the organisation in 2001. Notwithstanding, the Brazilian government found their share of support from other large emerging economies to backup their intention of both implementing and using the provision to ensure universal access to essential medicines. After finding consistent support from different international organisations, and given that further American commercial interests were also at stake, the United States of America withdrew the case before the DSB in July 2001.⁹⁷³

The Brazilian model resembles that the government is proactively and willing to protect internal concerns - both IP and public health related. Initially, IP reforms did not include all TRIPS flexibilities. However, during negotiations with the industry to obtain cheaper prices for the antiretroviral the government noticed its weaknesses and corrected them in a decent period of time. Given its condition as an emerging economy with high bargaining power, Brazil has managed to stay focused in tackling the HIV/AIDS epidemic, and hence access to essential medicines. Resisting immense pressure from trading partners like the United States of America has been a keynote in their success towards IP policies that are consistent with internal health concerns. Some have regarded the system as a system with no formal patent protection. However, if the patent system is to work

⁹⁷² Salama, B., and Benoliel, D., 'Pharmaceutical Patents Bargains: The Brazilian Experience' (2010) 18 *Cardozo Journal of International Law and Competition Law* 3, 1-31, at 9-20

<papers.ssrn.com/sol3/papers.cfm?abstract_id=1856629> accessed 10 September 2013

⁹⁷³ Gomes Brunner, A., 'As Patentes Farmacêuticas E A Licença Compulsória', at 28-30, Aslo See WTO DS199 Brazil — Measures Affecting Patent Protection, Current Status

<www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm, the case was settled on 19 July 2001> accessed 15 March 2014

in a way to boost national economies, inventive activities and transfer of technology, by Brazil protecting its national industry, it could be said that to a certain extent the goal of the patent system is not far from being reached within the Brazilian context.

Advancements within the public health care sector seemed to focus primarily on access to essential and HIV/Aids medication. Perhaps this shows that a clear focus, and policymaking continuity, are better than resetting the health care system and policies every time there is a governmental elect.

Thus, the Brazilian model or strategy of protection is based on high levels of bargaining power, local manufacturing capability and incorporation of TRIPS flexibilities, and safeguards within the national law may suggest that Brazil is a bargaining rebel.

6.1.2. Chilean Strategy

As an open market economy, Chile has signed FTA with around 50 countries, among them the United States of America. Thus, Chile not only ratified a TRIPS Plus Agreement but also implemented public health policies consistent with Chile's requirements to provide universal coverage.

The intellectual property legislation has been reformed so as to comply with its international commitments. However, TRIPS flexibilities had not been incorporated in full into their national system. Compulsory licences are foreseen to correct anti-competitive behaviour and also to address national emergencies. Thus far, Chile has never threatened to use a compulsory licence.

In terms of the IP Legislation per se, policy makers defined patents, patentability requirements that are generally not defined within other IP laws analysed.⁹⁷⁴ The Chilean legislation differs from the Brazilian most noticeably by the fact that no local working requirement is either envisaged to sanction a compulsory licence or conceived as a possible anti-competitive behaviour. In the case of unfair competition, "the competition court [is] the competent authority to determine whether or not certain practices are contrary to fair competition."⁹⁷⁵

Despite some authors considering that countries whom have signed TRIPS plus agreements tend to loose their bargaining power,⁹⁷⁶ the commercial exchange between Chile and other trading partners does not seem to be affected or to affect the health care quality. From a legislative standpoint, the correlation between the patent system and health care policies run in parallel without *strictu sensu* interfering with each other.

⁹⁷⁴ Ley N° 19.996. 3. Ley de Propiedad Industrial. Ministerio de Economía, Fomento y Reconstrucción, Santiago, Chile, marzo de 2006. Articles 31, 33,35-36

⁹⁷⁵ Ley N° 19.996. 3. Ley de Propiedad Industrial. Ministerio de Economía, Fomento y Reconstrucción, Santiago, Chile, marzo de 2006. Article 51 (1) requires from the Competition Court ruling where the practice or behaviour is deemed as such, before a compulsory licence can be enacted on the grounds of unfair competition.

⁹⁷⁶ Salama, B., and Benoliel, D., 'Pharmaceutical Patents Bargains: The Brazilian Experience' at 9

Admittedly, the US-Chile FTA brought certain concerns related to pharmaceutical patents. In principle, protection of undisclosed information and the use of the bolar exemption could have affected or impacted access to medicines in Chile. However, as the lessons from the Chilean health care system will portray, access to medicines in Chile is safeguarded and ensured by the State via other mechanisms that are not as aggressive as perhaps the ones used by Brazil.

Other issues brought by the FTA regard the pharmaceutical linkage imposed by this and the protection of test data information against unfair commercial use.⁹⁷⁷ Since the agreement was ratified in 2003, Chile has been constantly placed on both the Priority Watch List and Watch List in the yearly 301 Report from the Office of Trade Representatives from the United States. Thus, pharma related concerns are not the only ones mentioned or causing Chile to be placed in such a position before the US. In terms of the pharmaceutical linkage, it has taken several years for the Courts to acknowledge that sanitary permits are marketing approvals. Despite the fact, the Chilean legislation before ratifying the FTA foresaw the duty to inform right holders about applications from third parties, and also requested patent certificates.

As discussed within the substantive chapter, the consequences from the 301 Special Report from the Office of the United States Trade Representatives, could translate into commercial sanctions imposed on Chile. In the past, two tariff sanctions have been imposed to two other trading partners, whom ironically had not signed a FTA with the US. Any sanction to be imposed on Chile would require the trading partner to initiate the proceeding before the Dispute Settlement Body from WTO. If such a proceeding would take place, then the US would also have to evaluate the impact of this for its own commercial interests.⁹⁷⁸

Chilean politicians have been working, since the Chicago boys, to achieve greater national development through an open market economy. Therefore, Chile currently enjoys a rather stable economy gaining access to foreign markets, forming alliances to achieve greater public health awareness, and to boost their national pharmaceutical industry.

The current health care model has required many years of work to shape it into what it is today. Creating uniformity within the system, to make it available to all without discrimination, is what really ensures both universal access and coverage.⁹⁷⁹ Evidently, the system depends on high levels of funding to keep it running; it is primarily funded by taxpayers' contributions and other taxes imposed on determined items.⁹⁸⁰ Chile has also had its fair battle against HIV/AIDS, thus, this country has partnered up with Brazil to achieve greater

⁹⁷⁷ Marantis, D., The Office of the United States Trade Representative, *2013 Special Report 301* (May 2013) at 22,31

⁹⁷⁸ Keller, N., and Zanette, R., 'Los posibles castigos que enfrenta Chile' *El Mercurio*, 10 de Enero de 2007, at *Negocios y Economía*. Argentina was sanctioned by reducing in 50% the products within the Sistema Generalizado de Preferencia in 1997. Earlier on, Brazil had also been sanctioned with a tariff raise of 100% for several products, which could not be imported into the US between 1989 and the 90s

⁹⁷⁹ Borzutzky Yozmot, S., 'Social Security and Health Policies in Latin America' at 246-256

⁹⁸⁰ Borzutzky Yozmot, S., 'Health in Chile' at 645

international support from diverse organisations. By 2006, Chile was able to provide 100% coverage to treat the illness.⁹⁸¹

The Chilean model is based on commercial exchanges that allow them to allocate further funds into the development of the country. The liberal and market-oriented Chile has also seen how continuity and solidarity principles from all administrations benefit the overall development of the nation.

6.1.3. Venezuelan Strategy

In general terms, as the analysis of the 1955 IP Law shows, a significant setback for Venezuela's protection of both intellectual property rights and also access to medicines might have taken place by re-enacting this legislation.

As described above, the current IPR legislation foresees patents for inventions, discoveries and creations with the limitations denoted.⁹⁸² Thus, unlike Decision 486, the current Venezuelan IPR legislation fails to provide a definition as to what it is considered to be an "invention", however it tries to define it by providing a structure with four elements. This legislation grants and regulates patent rights from the inventor, the one who made the discovery and those who introduced the creations, inventions and discoveries relevant to the industry. Article 14 enumerates patentable matters and also states that generally everything resulting from someone's inventive effort taking into consideration legal exceptions shall be protected. Furthermore, it also enumerates the things that cannot be patentable.⁹⁸³

Following the discussion on whether or not discoveries are patentable, Decision 486 came to solve this issue to a certain extent. Given that patents were foreseen for inventions materialised in a product or a process including pharmaceutical products. This decision, as stated many times before, complied with the standards settled in the TRIPS Agreements.

Currently, as 1955's legislation is enforced in Venezuela, in theory patents for discoveries are allowed, whilst patents for pharmaceutical products are denied. Hence, defining what is considered to be an invention within the legal framework becomes, once again, a crucial issue. Beyond the legal uncertainty related to the applicable law, there is an important backlog of applications within the Patent Office to examine. Unclear rules may enable right holders to either receive protection or enforce their rights, and therefore under the Andean community umbrella there are a few legal remedies against SAPI that could and should be taken into consideration.

To start with, the legislation provides the possibility of taking over goods and rights, specifically patent rights, but when analysed in conjunction with LEXP there is not a single provision clarifying or guiding the procedure affecting patent rights. Several challenges are found, namely establishing the place for the expropriation decree publication affecting patent holder and third parties' rights. The legislation shows a weakness in determining valuation guidelines aimed to

⁹⁸¹ Editorial E.M., 'Medicamentos y AUGÉ', *El Mercurio*, 1° de Septiembre de 2006

⁹⁸² Article 30, Ley Propiedad Industrial – Venezuela supra note 248

⁹⁸³ Id Morles Hernández at 311

settle fair compensation of those rights or goods to be expropriated. The only guidelines or mandatory aspects to take into consideration by the appraisal commission are addressed to real state, personal property and goods with artistic, historic, architectural and archaeological value, but nothing within this 2002 LEXP addresses valuation of intellectual property rights, hence patents, to be expropriated by the National Government.

Furthermore, as early as 1965, Mariano Uzcátegui Urdaneta already advised the need to delimit in a clear manner, which is the procedure to follow in Venezuela regarding patent grant procedure. Given that, as highlighted above, there is no certainty on the timeframe to examine the novelty aspect beyond the opposition period that could happen either before or after publication. The same author brings to the spotlight disorganisation inside SAPI that already by 1965 made the grant procedure difficult and unclear. This specifically suggests, that previous examination could be performed before publications if SAPI organised itself for this matter and previous examination could also be performed after publications due to oppositions by designation of experts to carry on examination.⁹⁸⁴

At this point it is important to mention that utility models are protected within the scope of the Andean Community IP regime. Although these are not relevant for the protection of pharmaceutical products, it constitutes an important difference between the regime settled in Decision 486 and superseding, and the IP Law from 1955 that only protects models and industrial drawings.

Given the Andean Community's nature as an integration organisation, there are important inconsistencies between what should have been and what was done back then. To start with, the mere fact that Venezuela's Constitution was not at the same level as the integration process already poses an obstacle to reach common goals. Furthermore, important scholars suggest that becoming part of any integration agreement limits national powers and competences of constitutional courts and the "supra-national" character that these organisations portray.⁹⁸⁵

As highlighted within the discussion, in Proceso No. 03-AI-96 the Andean Court of Justice does actually assert that Venezuela was breaching the agreement and therefore was to be sanctioned. The threat was to raise export tariffs for Venezuelan products to any other country member, as inferred by the Summary Process following this decision. Within the same document it is found how the Venezuelan Government started taking measures to come into compliance by substituting an internal Regulation from the Agriculture Ministry in order to allow products in the conditions settled by the Agreement initially.

The IPR situation in Venezuela by no means seems to be an easy topic to address. Only a few authors have written about the national legal framework and its disparities. Use and misuses of IPRs are to be found, and the whole system seems to be at the edge of a cliff still debating on whether or not patents are detrimental for the access to medicines in Venezuela.

⁹⁸⁴ Uzcátegui Urdaneta, M., 'Sistemas de Concesión' in *Patentes y Patentes de Inversión en el Derecho Venezolano*, at 119

⁹⁸⁵ Brewer Carías, A., 'Implicaciones Constitucionales del Proceso de Integración en la Comunidad Andina', *Estudio para el Proyecto del Instituto de Estudios Internacionales (IDEI) de la Pontificia Universidad Católica del Perú, Perú, 2002.*

The current legal framework does not provide patent protection for pharmaceutical products. It has been argued by highly ranked officials how patents are a big detriment both to access to medicines and universal coverage granted by the Constitution⁹⁸⁶, hence justifying to a certain extent the rejection and silence in granting pharmaceutical patents since 2002.

Coming back to the legislative findings, it could be argued that Venezuela came into compliance with its international duties by implementing Decision 313, and later on 344 that adequate IPR standards to those settled in at the TRIPS Agreement. However, it can also be seen how the legislator's will collided with the President's in 2000 when direct implementation was achieved by publishing the aforementioned Decision within the country's Official Journal without formal parliamentary approval. At that time, the Venezuelan Constitution did not foresee direct and preferred implementation, as did the following amendment in 1999.

The differences between the scheme under Andean Community Law and the current national legal framework are evident; portraying the country's distance from complying with its international duties, for instance with the TRIPS Agreement. As widely discussed within the heading dedicated to Venezuela's withdrawal from CAN, until 2008 when SAPI enacted in its Official Journal an official communication disregarding Decision 486, the public in general understood as an integral part of the national system those provisions settled in the aforementioned framework. Furthermore, it is rather interesting that there are just a few Supreme Court rulings addressing the issue, but there is no formal ruling solving the constitutionality of SAPI's decision in 2008.

Going beyond the legal body per se, it is an interesting fact that after almost 6 years from the date when Venezuela withdrew from the Andean Community, there is not a single "proyecto de ley" (legislative project) presented for discussion before the National Assembly. One important difference between frameworks is the compulsory licensing regime, which to a certain extent may leave the country in a delicate position when facing national health emergencies.

Admittedly, compulsory licences are not the only legal mechanisms to protect public health, and in Venezuela "price control policies" as analysed above, become one of the preferred mechanisms to guarantee access to affordable medicines, which in reality might prove challenging considering the inexistence of a comprehensive list of illnesses covered in the country. Some illnesses are protected in Venezuela, and medication and treatment may be provided at affordable prices or even for free but there is general misinformation about the issue. It is important to mention that Venezuelans are heavily dependent on private insurance to cover their health care needs due to overload and inefficiency of public health care providers regardless of statistics showing significant governmental investment in the public health care sector.

Thus far the Venezuelan health system has been reshaped into a "mission" based one addressing primary, secondary and specialised attention. As highlighted above, inside the neighbourhood mission it is said to provide attention in rural areas, but further solving capabilities lead to create Barrio Adentro II –Inside the neighbourhood II- through the newly named Integral Diagnostics Centres –CDI-,

⁹⁸⁶ Samán, E., 'Patentes y Salud Pública', *Aporrea* (30 Septiembre 2007) <www.aporrea.org/tecno/a41884.html> accessed 10 March 2013

and Centres with High Technology – CAT. All of these aim to accelerate social integration while safeguarding universal human rights contained within 1999's Venezuelan political constitution –health, education, and place to live and work.⁹⁸⁷ These missions originated out of cooperation between the Cuban and Venezuelan Governments, and began operating at first as a pilot programme in a few barrios from the Metropolitan District where Cuban health practitioners treated those in need.⁹⁸⁸

On the one hand, health services are perhaps more accessible in rural areas, but on the other hand, rampant inequalities keep on emerging within the health sector. The fact that access to health care provided by Barrio Adentro is highly politicised, together with neglecting the existent public health care infrastructure are factors taking a toll on the private health care sector. Private health care providers are reported to be over crowded. Two of the reasons for this area lack of faith in the public sector and reluctance in receiving medical care from foreign doctors.⁹⁸⁹ Allegedly, private health care is only in reach of 3% to 4% of the total population who can afford to pay it. The rest of the cases or people seeking attention from them do it through private insurance policies, either individual or employment related, which is a clear indication of access inequalities.

Parliamentary Ismael García became very critical of the government policies in general, but regarding health care, he finds no reason for such a poor performance within the sector when considerable investments have been made to raise the level. He is also of the opinion that running a parallel system (Barrio Adentro), importing foreign doctors, discriminating national doctors and institutions are just some of the hypotheses leading the current system to fail.⁹⁹⁰

Rapid price increase in private health services due to high demand, lead to price regulations on behalf of the Government so as to ensure access. Accordingly, this measurement, where both the private health sector and Government agreed upon evaluating and determining singular fees for services and attention provided in clinics and hospitals, came after social pressure in recent months.⁹⁹¹

Another relevant challenge, relates to lack of resources to ensure quality, as both financial and human resources are needed to boost the public and private health sector. In the Wiki Leaks scandal a few years ago, something regarding the national health care system was also leaked. An important international journal pointed out the most important information contained in a cable sent from the Embassy of the United States of America in 2008, which addressed the exodus of

⁹⁸⁷ Alvarado, C., *et al.* 'Cambio Social y Política de Salud en Venezuela' Sección Especial: Reformas Progresistas en Salud, 3 *Medicina Social* 2, (Mayo, 2008) at 121

⁹⁸⁸ *Ibid* at 120

⁹⁸⁹ Dávila, E., 'Medicina Privada ¿Un negocio poco lucrativo?', 25 *VenEconomía Mensual: Industria y Comercio* (2008) at 1

⁹⁹⁰ Méndez Cegarra, A., 'El Sector Salud en Venezuela, tanto público como privado, anda de mal en peor' <ismaelgarcia.net/home/index.php/el-sector-salud-en-venezuela-tanto-publico-como-privado-anda-de-mal-en-peor/> accessed 15 June 2012

⁹⁹¹ Efe Agencia, 'Acuerdo del Gobierno y La Patronal Médica: Venezuela: Congelan las tarifas en salud privada', *Los Tiempos*, 17 August 2011

Venezuelan doctors to foreign countries offering better labour conditions than the ones found at home among other things.⁹⁹²

The lack of financial resources within the public health care sector has never been a secret either; the Bermudez vs. Ministerio de Sanidad y Asistencia Social (Ministry of Health) case is a vivid example of how priorities are managed in Venezuela. This case highlighted not only the incompetence of the Government to offer decent health care, but also demonstrated that pharmaceutical patents did not have anything to do when denying access to health care. In this case the Supreme Court failed in favour of an HIV patient who did not receive adequate treatment even though he had the right to access public health care.⁹⁹³ It was the first time that a Court recognised a lack of budget to provide proper public health in the country. The Courts' ruling was deemed to create social concern towards health care needs.⁹⁹⁴

Besides the current legal uncertainty surrounding the country in general, other issues collide with constitutional rights like access to proper health care and the emerging "right to health".⁹⁹⁵

⁹⁹²Peregil, F., 'Ábrelo y di ahhh: Sistema venezolano de salud', *El País*, 9 March 2011. <www.elpais.com/articulo/internacional/Abrelo/di/ahhhh/Sistema/venezolano/salud/elpepuint/20110309elpepuint_14/Tes>accessed 6 June 2012

⁹⁹³Cruz Bermúdez, et al v Ministerio de Sanidad y Asistencia Social, Sala Político Administrativa, Corte Suprema de Justicia, República de Venezuela, Expediente Número 15.789 (1999)

⁹⁹⁴Torres, M., 'The Human Right to Health, national Courts and Access to HIV/AIDS Treatment: A case study from Venezuela' (Spring 2002) *Chicago Journal of International Law*, at 105

⁹⁹⁵Gathii Thuo, J., 'The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties' *15Harvard Journal of Law & Technology* 2, at 305

7 CONCLUSIONS AND SUGGESTIONS: WHERE DO WE GO FROM HERE ONWARDS?

Disease is largely a consequence of poverty and of governments being unable or unwilling to undertake the public health measures to eradicate them.⁹⁹⁶

This doctoral dissertation's main focus was to analyse the relationship and conflict between pharmaceutical patents and access to medicines within a specific geographical context, namely Brazil, Chile and Venezuela. Thereafter, it asked what strategies are used to balance patents and public health concerns, as it was largely established within the previous chapters.

Having defined the focus, the dissertation was structured in a manner that allowed the doctoral student to address three main objectives: (a) to understand the patent and health care systems at a national level in each context; (b) to review the challenges related to access to medicines to see if any derived from the implementation of the TRIPS Agreement; and (c) to learn how countries balance these rights, if at all, and what strategies are used (Rebel Brazil, "Liberal" Chile and In Limbo Venezuela).

The findings have been presented within the descriptive chapters where each country is analysed on a case-by-case basis. However, given the comparative nature of the current dissertation these findings are discussed in two stages: within the general summary, which provided the general framework and also identified the strategies or models of protection; and in this chapter, which aims to discuss and present the reader with the conclusion on the dissertation's main goal - to determine whether or not Venezuela can benefit from implementing a similar strategy to the one used in either Brazil or Chile. This was done keeping in mind its purposes in creating knowledge, demystifying the patent system, and raising awareness on the need for major governmental involvement to balance rights while at the same time ensuring people's access to medicines.

By delimitating the context of the discussion about access to medicines, it is possible to both find plausible solutions addressing patents and access to medicines, and to demystify the patent system that has proven to be relevant for some developing countries' economies e.g. Chile.

Given the difference in the strategies used by Brazil and Chile, the lessons are intended to portray the strength of each strategy. In other words, the Brazilian strategy heavily relies on the use and implementation of TRIPS flexibilities while at the same time strengthening its public health policies. In contrast, the Chilean strategy seems to rely on health care policy implementation, therefore the lessons will focus on this development since there are only a few controversies relating to pharmaceutical patents.

⁹⁹⁶ Acemoglu, D. and Robinson, A., *Why Nations Fail: The Origins of Power, Prosperity and Poverty* (Profile Books: London, 2013) at 51

7.1.1. Lessons from Brazil and Chile in Terms of Patent Protections

From an institutional standpoint, both Chile and Brazil provide a comprehensive legal framework for intellectual property rights protection. However, each of the countries implemented the Agreement in a different manner and time. Brazil did not make use of the transitional period given to developing and least developed countries to implement the Agreement, whereas Chile did make use of it and actually ended up implementing the TRIPS Agreement and TRIPS plus provisions within the national legislation almost at the same time.

Each country had a different set of challenges, and a different strategy or model of protection. Both Brazil and Chile have opened their markets to foreign investments and competition aiming to become part of the globalised prosperity envisaged with the creation of the WTO.

The impact of TRIPS in Brazil does not seem to be clear. On the one hand, INPI reported an increase in patent applications for pharmaceutical products mostly from foreign companies.⁹⁹⁷ But on the other, given the sharp decline in the national pharmaceutical industry's productivity, Brazilian also saw a rise in its own generic industry.⁹⁹⁸ The rise of this industry in particular is also intertwined with public health policies, i.e. the Generics Drug Law. Data collected by the Brazilian government shows an increase of nearly 224% in Brazilian imports in total in the period 1982-2002, and imports of pharmaceutical products grew by 6,112%.⁹⁹⁹

It is important to remember that to this date Brazil has no FTA with any other major industrialised country, thus higher standards of protection have not been implemented in Brazil via FTAs. Admittedly, the caveat in implementing TRIPS relies on the import data indicating that the national industry might not –after all– benefit from pharmaceutical technology transfer if limited manufacturing capabilities prevail in the country. Nevertheless, Agreement, Lei n° 9.279 (IP Code) and the following amendment in Lei n° 10.196 seem to have been implemented in a manner consistent with national needs, perhaps mainly health related. Implementing the TRIPS Agreement in Brazil happened at the same time that the country was implementing health reforms, restructuring the health care system amid HIV/AIDS crises. The research brought to the spotlight several important reforms that were addressed to both lowering drug prices and increasing affordability and availability of ARVs. Increasing availability also implied increasing the national generic industry's manufacturing capability that was to be in jeopardy due to the implementation of TRIPS since patented drugs could no longer be copied.¹⁰⁰⁰ Thus, the amendment to the IP Code set forth the

⁹⁹⁷ Oliveira, M., and Bermudez, J., et al., 'Pharmaceutical Patent Protection in Brazil: who is benefiting?' in *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health*, Jorge A. Z. Bermudez, and Maria Auxiliadora Oliveira (eds.) WHO/PAHO Collaboration Center for Pharmaceutical Policies National School of Public Health Sergio Arouca Oswaldo Cruz Foundation, (Nucleus for Pharmaceutical Policies (NAF)/ENSPSA/FIOCRUZ: Rio de Janeiro-Brazil, 2004) 163-177, at 176 <www.law.fsu.edu/gpc2007/materials/LivroTRIPSEnglish2004.pdf> accessed 10 September 2013

⁹⁹⁸ Salama, B., and Benoliel, D., 'Pharmaceutical Patents Bargains: The Brazilian Experience' at 7

⁹⁹⁹ Oliveira, M., and Bermudez, J., et al., 'Pharmaceutical Patent Protection in Brazil' at 173

¹⁰⁰⁰ Nuun, A., 'The History and politics of AIDS' 91

compulsory licence regime, and also the prior consent mechanism to ensure –to a large part- its governmental commitment in fighting HIV/AIDS.

Two other controverted issues within the IP Code are the local working requirement, and parallel imports; both “mechanisms” seem to have been envisaged following the need to ensure the country’s availability and affordability of medicines. Even when the legislation, as it is, portrayed strong commitment and awareness of national interests in 2013, the Bill no. 5402/2013 (hereinafter the Bill) was introduced before the congress for consideration to reform the current IP Code. This Bill aims at providing Brazil with an IP framework more suitable to its current challenges, and also to take further advantage of TRIPS’ flexibilities. The analysis introducing the Bill highlights that if patent law is duly balanced with other fundamental rights, as provided by the Constitution, then the patent system will promote technological development while striking a balance between exclusivity and competition.¹⁰⁰¹ Fulfilling Article 5 of the Brazilian Constitution –social function- seems to inspire in substantive parts this proposal for reform, the goal of which is to foster an environment for innovation in the country that will translate into both productivity and the foundations for the Brazilian society’s sustainable development.

Within the previous chapter, depicting the strategy of model of protection, particular attention was given to Article 4 from ANVISA’s Resolution RDC n° 21 due to the fact that patentability requirements still seemed to be under the agency’s scrutiny despite controversy related to misunderstanding its attributions or limitations to examine patent claims. Furthermore, the Newton Lima Bill –as it is also known- confirms the interpretation of the Article 4 y by not only making reference to the newly reformed Resolution, but also by providing ANVISA with a series of recommendations on how to verify that patent applications fulfil patentability requirements in light of the public health context; ones that do not necessarily differ from the suggestions given to the patent office on the same issue.¹⁰⁰² The proposal to reform the current intellectual property regime will be discussed during 2014.¹⁰⁰³

The lesson from the Brazilian IP law regime in terms of patents and access to medicines relies on the way policy makers have tailored and are still tailoring the

¹⁰⁰¹ *Brazil’s patent reform [recurso eletrônico]: innovation towards national competitiveness /* coordination: Newton Lima; technical team: Pedro Paranaguá (coord.) ... [et al.] Maíra Mendes Galvão (translator). -- Dados eletrônicos. -- Brasília : Chamber of Deputies, Edições Câmara, 2013. -- 1(Série estudos estratégicos; n. 1) 1-363, 9

¹⁰⁰² Idib 68-69

¹⁰⁰³ Barbosa, D. (2014) commented on the process prior the approval or discussion of the Bill within the context of the pre-examination of this research. In that respect he pointed out “Procedurally, the Bill was attached and bundled to all other prior patent-related bills in course in the lower house (10-12). Just the biotech and plant varieties bills were kept unbundled, as the Bill does not cover such areas. The consequence of such bundling is that the senior Bill leads the procedure, and therefore the whole is now submitted to the Constitutional Commission, the role of which is to check whether the proposal might pass the constitutional filter and whether it is viably drafted. The next step would be to carry the bundle to the vote of full chamber. What will happen there is virtually unpredictable.” Also see, Licks, O. ‘The Brazilian IP community has great expectations for 2014, despite distracting events: a carnival in March, the FIFA World Cup in June and elections in October’ *World Intellectual Property Review*, 01 February 2014 <www.worldipreview.com/article/brazil-what-to-expect-in-2014> accessed 3rd April 2014

TRIPS implementation within the country. Even though the Agreement settles minimum standards of protection, this also provides a set of flexibilities that can be used in favour of the country implementing the Agreement.

The minimum standards of patent rights are established by the WTO TRIPs Agreement, that leaves considerable room to adapt each country's patent laws to their own reality and current stage of technological development, and social and economic needs.¹⁰⁰⁴

It has been suggested that Chile only implemented higher standards of protection since ratifying the US-Chile FTA, as this was the legal framework actually compelling Chile to reform their national IP law.¹⁰⁰⁵ Admittedly, the Chilean IP law may be among the most sophisticated laws drafted in the region, since this even provides definitions for inventions and patentability requirements, which generally are not defined, but enunciated, within the legislation.

Moreover, the legislation includes a provision granting protection to undisclosed information within the context of supplementary terms of protection as provided by the FTA. This provision aims at not only preventing the National Health Institute or third parties from making use of sensitive information to grant marketing approvals, or sanitary authorisation as regarded by the law, for similar products without the originator's consent, but also at delimitating the scope of the supplementary term of protection that ought to be granted due to unreasonable curtailments of time in granting patent protection¹⁰⁰⁶

Artículo 53 Bis 2.- Dentro de los seis meses de otorgado un registro sanitario de un producto farmacéutico protegido por una patente, el titular tendrá derecho a requerir un término de Protección Suplementaria para aquella parte de la patente que contiene el producto farmacéutico, siempre que haya existido demora injustificada en el otorgamiento del señalado registro. Podrán requerir esta protección suplementaria, aquellos titulares cuya autorización o registro sanitario haya sido otorgado después de un año contado desde la fecha de presentación de la solicitud. La protección suplementaria se extenderá sólo por el período acreditado como demora injustificada por parte del órgano administrativo encargado de resolver dicho registro.¹⁰⁰⁷

The legislation, by implementing the provisions within the FTA, sets forth the linkage between the patent office and the national health institute. Initially this was only between the need to communicate third parties about prior and existing patents rights. However, with the test data protection provision the legislation now foresees the possibility in granting a supplementary term of protection due to administrative curtailments of time in granting marketing approvals. In other words, a right holder may be entitled to receive a supplementary time of protection if either the patent offices takes longer than envisaged by law to grant the patent and/or if the national health agency takes more than a year to grant the marketing approval. In this respect, the legislation also clarifies the circumstances that cannot be understood as unreasonable curtailments of time; namely, oppositions presented before the Agency, waiting for reports from competent authorities that are also relevant for the process and actions and

¹⁰⁰⁴ Lima, N. 'Brazil's patent reform', 16

¹⁰⁰⁵ Salama, B. and Benoliel, D., 'Pharmaceutical Patents Bargains: The Brazilian Experience' at 9

¹⁰⁰⁶ Ley N° 20.160. 3. Revised, Coordinated and Sistematized Text of the Industrial Property Law. Ministerio de Economía, Fomento y Reconstrucción, Santiago, Chile, marzo de 2006. Article 53 bis(2) <www.wipo.int/wipolex/es/text.jsp?file_id=270135> accessed 15 September 2013

¹⁰⁰⁷ Ibid Article 53 bis 2 from the Ley N° 20.160

omission on behalf of the right holder.¹⁰⁰⁸ In light of this provision it may be feasible to assert that a linkage has been set out in both directions. On the one hand, the INPI is to grant a supplementary term of protection due to unjustified delays in marketing approvals, and on the other hand, the national health agency is to acknowledge the existence of patent right and also to inform the right holder if third parties are intending to commercialise a similar product to the one patented and commercialised by the originator.

Chile, in the first instance, denies patents for second uses, but then presents the exception within the same article by establishing that patents for second medical uses can be granted if patentability requirements are met.¹⁰⁰⁹ Admittedly, this article, at first glance, seems rather confusing, and in this context it has also been argued that patents could be extended if a second use is considered to meet patentability requirements.¹⁰¹⁰

Non-voluntary licences are also foreseen within the context of the Chilean IP law. However, the local working requirement set out in the Brazilian IP law is not. Article 51 envisages the use of non-voluntary licences to correct anti-competitive practices, which need to be determined by the Competition Court; to address national emergencies, public health, national security or any other situation of extreme urgency that will also need to be declared by the competent authority. The last provision allowing the use of compulsory licences seems to be more of an exception among the exceptions that a compulsory licence *per se* is allowed to be used. In this respect, Article 51 (3) allows a non-voluntary licence when the third party needs to make use of a posterior patent, and this one cannot be used without infringing the previous patent.¹⁰¹¹ Thus far, Chile has not made use of either the threat to use or actually issued a non-voluntary licence to address any of the cases provided within the framework.

Thus far, the Chilean IP lesson portrays how the country has aligned national interests within the sphere of international commercial exchanges. In terms of policy-making, all provisions prompted within the FTA, although reluctant to admit linkage, were actually implemented in the national IP law. The fact that no sanction has been imposed on Chile for those 'IP concerns' may reflect that

¹⁰⁰⁸ Article 53 bis 3 from Ley N° 20.160. 3. Revised, Coordinated and Sistematized Text of the Industrial Property Law.

¹⁰⁰⁹ Article 37 (e) from Ley N° 20.160. 3. Revised, Coordinated and Sistematized Text of the Industrial Property Law. "e) new uses, the shape change, size change, changing proportions or changing the material of articles, objects or elements known and used for certain purposes. Without prejudice of the aforementioned, it may also constitute an invention new use of articles, objects or elements known, provided that the new use solves a technical problem without previous equivalent solution, meets the requirements settled in Article 32 and requires a change in the dimensions in the proportions or durable materials or known object to obtain a solution to the aforementioned problem. The claimed new use shall be justified by experimental evidence in the patent application." (original text in Spanish, translation provided by the author)

¹⁰¹⁰ Rodríguez Spinelli, F., 'El Sistema de Patentes y el Desarrollo Tecnológico: algunas Consideraciones en el Marco de la Libre Competencia' 11 *Revista Propiedad Intelectual* (2008) 87-109, at 101

¹⁰¹¹ These kind of patents have been defined or referred to within the legislation as 'dependent patents'. Article 51 (3) "Cuando la licencia no voluntaria tenga por objeto la explotación de una patente posterior que no pudiera ser explotada sin infringir una patente anterior. La concesión de licencias no voluntarias por *patentes dependientes* quedará sometida a las siguientes normas:"

commercial interests of both parties are a heavier burden than lobbying for a 'perfect IP system'.

7.1.2. Lessons from Brazil and Chile in Terms of Access to Medicines and other Public Health Issues

Providing access to affordable essential medicines is one of the goals pursued by developing countries. However, as it has been argued, this access seems to be in jeopardy due to intellectual property protection. Before reaching a conclusion on whether patents are deterring access to medicines in Brazil, Chile and Venezuela, it is important to address the lessons from Brazil and Chile in terms of public health policies and structure. Given that the substantive chapters analyse the current health care system and policies within the aforementioned context, this section will be limited to addressing the main characteristics of each system.

Structural, practical and theoretical differences are observed. Both Brazil and Venezuela have Mixed National Health Systems (MNHS), which are characterised by having different funding sources within the public sector. In contrast, the Chilean health care system is based on the National Social Health Insurance System (NHIS) and has an important distributive impact on the government's health expenditure: about 31% of the expenditure is accrued from the population within the poorest sector,¹⁰¹² thus the political Constitution provides universal coverage, financed via taxpayers' money and mandatory contributions to fund the health care system.

The Chilean health care system is based on four guarantees or principles: access, quality, opportunity and financial protection.¹⁰¹³ In contrast, the Brazilian system does not specifically mention either quality or financial protection, but this does not mean that universal coverage is not given. As the analysis shows, both countries provide universal coverage, and both countries have strong public health policies addressing availability and affordability of medicines. International experience has proven that countries with a "strong State" are the only ones able to provide efficient, effective and equitable health care for everyone. This is so because strong states are capable of regulating, taxing and making proper disposition and administration of governmental funds.¹⁰¹⁴

Both countries have comprehensive National Charts of Essential Medicines. The difference is in the fact that the Chilean one includes medicines to treat either high-cost or catastrophic and common illnesses, whereas the Brazilian one covers most of the common diseases (HIV/AIDS among them), with the so-called high-cost medicines being envisaged within a separate framework.

In 2006 at the UN General Assembly an organisation named UNTAID was launched under the auspice of several developing and least developed countries,

¹⁰¹² Rubén Suárez – Berenguela, 'Health system inequalities in Latin America and the Caribbean: Findings and policy implications' Working paper prepared for the Health and Human Development Division of the Pan American Health Organization-World Health Organization (January, 2000) at 27

¹⁰¹³ Biblioteca Nacional del Congreso de Chile, "Guía Legal sobre Plan GES" in Ley Fácil, available only in Spanish at : <<http://www.bcn.cl/guias/plan-ges-ex-aug>>

¹⁰¹⁴ Jaén, M., '¿Por qué un estudio sobre el costo del sistema de salud en Venezuela?' at 40.

among them Brazil and Chile. UNAID is dedicated to “provide regular, sustainable, predictable, additional, long-term financing for drugs and diagnosis for AIDS, tuberculosis and malaria for use in developing countries.”¹⁰¹⁵

The Brazilian model is widely praised for the undeniable success in battling HIV/AIDS. It is said to be an important key player in changing or influencing global health care policies in terms of the illness. At the same time, also key to their success are the following factors: developing their national generic industry, fearless use of compulsory licences to reduce ARVs prices and using the human rights doctrine to shape their internal essential medicines policies.¹⁰¹⁶ In the fight against HIV/AIDS, Brazil has implemented a series of measures addressing access to affordable medicines if they cannot be provided for free. The Popular Pharmacy Programme intended to reach rural areas while ensuring affordability and availability of medicines. This programme allows patients to cover only 10% of the full cost of the medicine since the government subsidises 90% of the price.¹⁰¹⁷

Brazil relies on public procurement practices to purchase the essential medicines that are distributed within the health programmes in the country. Procurement was initially centralised under CEME, but later on amid corruption issues the system was decentralised allowing every state to purchase their own medicines. Even though procurement is decentralised, the country still reserves the right to centralise the procurement of medicines addressed to tackle an illness of such magnitude that at the same time poses a severe risk to public health, i.e. HIV/AIDS crisis.¹⁰¹⁸ Despite the analysis focusing primarily on the aforementioned illness, it is important to highlight that other medicines are also purchased by the Federal Government to thereafter provide them at affordable prices. Medicines for malaria, Hansen’s disease, cholera, haemophilia, diabetes,

¹⁰¹⁵ Bermudez, J. and ‘t Hoen, E., ‘The UNAID Patent Pool Initiative: Bringing Patents Together for the Common Good’ in *The Open AIDS Journal*, 2010, 4, pp 37-40 at 37

¹⁰¹⁶ Nuun, A., et al. ‘Changing Global Essential Medicines Norms to Improve Access to AIDS treatment’ at 134-138

¹⁰¹⁷ See further, Du Borage Santos Pinto, C., et al. ‘Medicines prices and availability in the Brazilian Popular Pharmacy Program’ 44 *Revista de Saúde Pública* 4 (2010) 1-8

¹⁰¹⁸ Nuun, A. ‘The Politics and History of AIDS’ at 108; also see Brasília, Ministério da Saúde – Secretaria de Políticas de Saúde, Departamento de Formulação de Políticas de Saúde, Portaria nº 3.916/GM em 30 de outubro de 1998, Política Nacional de Medicamentos. Artigo 3.3 “A assistência farmacêutica no SUS, por outro lado, englobará as atividades de seleção, programação, aquisição, armazenamento e distribuição, controle da qualidade e utilização - nesta compreendida a prescrição e a dispensação -, o que deverá favorecer a permanente disponibilidade dos produtos segundo as necessidades da população, identificadas com base em critérios epidemiológicos.

No tocante aos agravos e doenças cuja transcendência, magnitude e ou vulnerabilidade tenham repercussão na saúde pública, buscar-se-á a contínua atualização e padronização de protocolos de intervenção terapêutica e dos respectivos esquemas de tratamento.

Assim, o processo de descentralização em curso contemplará a padronização dos produtos, o planejamento adequado e oportuno e a redefinição das atribuições das três instâncias de gestão. Essas responsabilidades ficam, dessa forma, inseridas na ação governamental, o que deverá assegurar o acesso da população a esses produtos. Para o Ministério da Saúde, a premissa básica será a descentralização da aquisição e distribuição de medicamentos essenciais”

schistosomiasis, trachoma, leishmaniasis and filariasis are also among the medicines provided by the Ministry of Health.¹⁰¹⁹

Scholars have also attributed the success of the Brazilian health care system to both linking prevention and treatment and to the intertwined development of public health policies with intellectual property legislation.¹⁰²⁰ Admittedly, the development and sustainability of the AIDS treatment programme became challenged when Brazil became a WTO member country. Nonetheless, and even when the country did not make use of the 'period of grace' to implement the Agreement, Brazil instead used innovative strategies to promote access to medicines for the treatment of HIV/AIDS,¹⁰²¹ and also found away to implement the flexibilities within TRIPS to ensure the programme's sustainability.

The lesson to learn from Brazil in terms of public health development is also based on the continuity and solidarity with the Brazilians on behalf of their policy makers. Changing the strategy as soon as a new administration is elected would not have led to the system that they have today. Politicians remain aware of the challenges, thus the changes made in the context of health care policies have only improved the system.

Chile on the other hand, developed one of the most complete health care systems in the region. Allegedly, this is the only system that grants real universal access to both health care and medicines. Chile has also been prized for their efforts in battling HIV/AIDS within the country.¹⁰²² Health care reforms have taken several years to build the system into the current one, and perhaps their strategies have not been as aggressive as in Brazil. Investing in infrastructure, human resources and implementing adequate health care policies are key factors determining the country's success. Close cooperation with the Pan-American World Health Organization, World Health Organization and working with diverse groups lobbying for affordable medicines have also played an important role.

Accordingly, Chile has implemented and follows the guidelines given by WHO for the mass scale purchase of medicines. The Central Procurement Office (CENABAST) is in charge of standardising acquisition processes to ensure availability and affordability of essential medicines.¹⁰²³ CENABAST is functionally decentralised, which differs from the Brazilian procurement system because this one allows every county to purchase its own medicines, but independently of the prevalent system in each country, with each of them being able to provide citizens with essential medicines at affordable prices if not for free.

At some point in Chile, competition within the pharmaceutical sector was encouraged to decrease medicines prices. However, pharmacy chains demonstrated aggressive practices that were a detriment to smaller pharmacies. The government had to both subsidise medicines and also negotiate directly with the industry (in the case of ARVs) to obtain reduced prices. Chile is one of the

¹⁰¹⁹ Galvão, J., 'Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health' (July 2005) 95 *American Journal of Public Health* 7, 1110-1116

¹⁰²⁰ Idem

¹⁰²¹ Nuun, A. et al., 'AIDS Treatment in Brazil' 1107

¹⁰²² Editorial E.M., 'Medicamentos y Auge' (2006)

¹⁰²³ Decreto Ley N° 2.763, Creating the Central Procurement Office of the National Health Service System (SNSS) Article 46

South American countries with the lowest average price for medicines. Reducing out of pocket expenditure was also important to ensure people's access to medicines. The use of traditional medicines is also encouraged by the Ministry of Health who has provided guidelines for the use of herbal medicines in certain cases. Rational use of medicines has also been encouraged both by Chile and Brazil and international organisations.

Chilean health care is another example of having a common goal embedded in the society, since every administration has worked towards achieving higher standards of health care. Relying on national GPD, taxpayers' contributions and other taxes seems to have sufficed to cover the costs derived from the health care system.

7.1.3. Could Venezuela Learn from either Brazil and/or Chile: How could these Lessons be implemented?

The initial goal of this research was to define the role of pharmaceutical patents within the Latin American development and to find whether or not patents play an important role when delimitating public health policies. Due to the geographical extent, the research focused on three relevant but distant countries: Brazil, Chile and Venezuela.

Understanding how the health care system works in each country was of vital importance before analysing the role of patents. The importance of this assessment relies on the fact that the author needed to address the governmental commitment of those countries surveyed before reaching the simplistic conclusion that patents are the main reason hampering access to medicines in developing nations. Patents may contribute to raise the prices of medicines, but as the study shows, there are countries with a more or less balanced health care system where not only are pharmaceutical patents protected but also health care and access to medicines is provided.

The research began with the idea of comparing three different patent systems, which were initially thought to be at a comparable level. All three (Brazil, Chile, and Venezuela) had effectively implemented TRIPS' minimum standards of protection. In the following years, Venezuela withdrew from the Andean Community and re-implemented its IP Law from 1955, which is not in line with TRIPS.

Pharmaceutical patents may influence people's ability to access affordable medication, but there were also indications of other factors taking prevalence over patent issues when ensuring access to medicines. Therefore, this dissertation analysed both intellectual property rights and public health frameworks at a national level, taking into consideration legal, social and political aspects present in the discourse. The aim was to identify not only the strategies or models of protection, but also the relevance of the patent system within the development of health care policies. The international debate and developments were also important in order to understand the rationale for determined measures in determined contexts, such as prior consent mechanism in Brazil.

Within the early stages of the research certain developments brought to the spotlight the lines of thinking followed by each country, hence framing the

strategies or models of protection. For instance, Brazil (The Bargaining Rebel), strongly protects public health but also implemented the TRIPS Agreement into its national law attempting to bypass the negative repercussions that could have been brought upon their fight against HIV/AIDS. Chile (The Commercial Liberal), did not only implement TRIPS, but also higher standards of protection with the US-Chile FTA while at the same time taking care of public health concerns. And Venezuela (In Legal Limbo), which is politically active and strongly oriented towards 'socialism' and going through a transitional period, implemented TRIPS but rapidly went back to the previous legislation thus placing the country in legislative uncertainty.

Despite having different strategies of protection, the interesting part of the research was determining if and how Venezuela could benefit from implementing either a similar strategy to the ones used in either Brazil or Chile or simply by reforming its national patent law in a manner consistent with Venezuela's needs. Before stating the conclusion and the rationale behind it, it is also important to mention the limitations encountered while carrying out the research that constrained the analysis to a review and interpretation of national literature, legislation and case law. Although case law was not constantly available in its digital form, and in certain contexts there was limited literature written from the national perspective, this research intended to portray interpretation and implementation issues in each country from their very own perspective. The aim was to provide the reader with the specific context in each country, thus avoiding or reducing the risk of transplanting foreign institutions. Among the limitations, language issues are also to be mentioned particularly because there is always a risk in misguiding the interpretation of national precepts when translated into foreign languages. However, the conversations and guidance provided by experts in the field in each country aimed at both reducing such a risk and also at gaining further insight about the situation in each context.

After carrying out the analysis in the substantive chapters and also referring to part of the comparative discussion it can be concluded that Venezuela could not only learn from the strategies used in Brazil and Chile, but that it is also in a 'privileged position' in terms of implementation and balancing rights. By no means does this statement agree with voiding the patent system or unfulfilling international commitments, such as implementing TRIPS since Venezuela is also a WTO Member.

The rationale behind stating that Venezuela seems to be in a 'privileged position' – in terms of the TRIPS implementation- is because tailoring the implementation of TRIPS in Venezuela in a manner consistent with national health policies, would seem to be a natural step for Venezuela so as to balance rights, boost national growth, foreign investments and contribute to legal certainty. Such implementation could help ensure for citizens the enjoyment of their human right for the highest attainable standard of health, but only if public health policies are also implemented in parallel. I will elaborate further about this argument when addressing the Brazilian compulsory licence regime.

Admittedly, intellectual property rights are not a priority within the Venezuelan context. However its membership in WTO and MERCOSUR call for the country to engage in legal reforms to implement minimum standards of protection if

Venezuela in the long run is to continue enjoying the prerogatives derived from trade agreements and the organisational integration.¹⁰²⁴

The current IP law in Venezuela differs from TRIPS in several aspects: patentable subject matter, term of protection, patent grant procedure, disclosure and compulsory licence regime. Thus, two of the aspects where Venezuela could benefit greatly from tailoring IP law implementation relate to disclosure, and compulsory licence regime. In terms of disclosure, Article 59(2) from the IP law of 1955 required patent applications to attach a comprehensive description of the inventions. The provision requests for “clear description of the patentable subject matter, with complete and exact directions on how operates, and what was the method used to build it, create it or mix the invention.” And the TRIPS Agreement in Article 29 requires for applicants to “disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.” At first glance, it seems that the disclosure required within the current Venezuelan law may be slightly higher than the one settled in TRIPS, and perhaps even resembles the requirement to disclose the *best mode*.¹⁰²⁵

In terms of the compulsory licence regime, the Venezuelan law is at disadvantage in comparison to other countries that have implemented the Agreement. Thus far, compulsory licences are not foreseen within the current legislation, and the only legal mechanism to address public interest (as public health in this case) is via expropriation procedures. This has proven to be the latest Venezuelan trend to “solve” “public interest” concerns, such as those a significant part of the agricultural industry has experienced over the last 14 years. The challenges related to intellectual property expropriation have already been described within the substantive chapter.

The Brazilian strategy, in terms of TRIPS implementation, maybe suitable for Venezuela, since the Venezuelan discourse portrays a strong inclination towards the protection of public interests, and therefore public health aiming to provide universal coverage. Moreover, if Venezuela would implement a compulsory licence regime similar to the Brazilian one, perhaps the country will be able to promote the development of the national generic industry by setting out the local working requirement to avoid patents being granted without actually making use of patent rights in the country. If a compulsory licence regime would be in place to tackle national health crises, perhaps Venezuela could even threat to use or even issue a compulsory licence to obtain better medicine prices thus allowing Venezuelans to have access to both affordable and availability of medicines. The system in Brazil has proven advantageous in achieving lower medicine prices to address the HIV/AIDS epidemic. Thus, this could be a means for Venezuela to

¹⁰²⁴ Protocol of Harmonization Norms on Intellectual Property in Mercosur in matters of trade marks, indication of source and appellation of origin, Dec. No. 08/95, signed in Asunción, 5 August 1995

¹⁰²⁵ Even when the best mode doctrine was not assessed within the research, this is to be understood as: “The best mode requirement holds that a patent applicant must disclose in a patent specification the best embodiment or “mode” of practicing the invention claimed by the patent’ See 35 U.S.C. § 112 (2006), and also see Petherbridge, L., and Rantanen, J., ‘The Pseudo-Elimination of Best Mode: Worst Possible Choice?’ (2012)59 *UCLA Law Review of Disclosure*, 170-177

incorporate one of the TRIPS flexibilities into the national framework and to also increase bargaining power to achieve affordable access to determined medicines.

Nonetheless, there is a caveat to this suggestion, if the legislation is not drafted in a clear manner setting forth the limits of the flexibilities incorporated - how and when is to be used - the legislation would not serve with the purpose of clarity and predictability required to both define and typify an act before the law. Reforming the national health policies and extending public procurement practices to lower medicine prices would also need to be established for the compulsory licence regime to serve its purpose.

The Brazilian IP Code in Article 68, establishes the use of compulsory licences to: (a) correct anti-competitive practices, abusive behaviours; (b) satisfy the local market when either there is no sufficient supply, or because the patent holder has not worked the patent within a period of 3 years from the date this was granted – unless economical unfeasibility can be proven or force majeure; and (c) deal with cases of national emergency or public interest. But the current Venezuelan IP Law in terms of anti-competitive practices also foresees the expropriation procedure to correct them. As highlighted within the substantive chapter, the terms and conditions to carry out such a procedure in the case of pharmaceutical patents or even intellectual property rights is not clear.

'Nulla poena, sine lege' traditionally allows the imposition of sanctions on determined behaviour that has been previously typified within a law. But how can or could Venezuela correct an-anti competitive behaviour with a compulsory licence if this provision has not been implemented within the internal legislation.

Price control, money control policies, and an out-dated IP legal system are just three of the factors from a legal and economical point of view impeding access to affordable medication in Venezuela. On the one hand, prices are controlled, but on the other, foreign currency is exchanged at staggering prices in the parallel market since currency at the official rate is not awarded or available with the speed and efficiency that the industry requires.¹⁰²⁶

The other provision that could be implemented into the Venezuelan system is the Prior Consent mechanism. This mechanism was implemented in Brazil after negotiations in 2001 with the pharmaceutical industry brought to the spotlight certain weaknesses in the patent system when taking into consideration the impact of pharmaceutical patents over public health needs. If Venezuela were to implement a similar mechanism that would assess the impact derived from granting a pharmaceutical patent, perhaps even the local industry and universities carrying out R&D could actually benefit from patent protection. Nevertheless, the attributions from the National Health Institute in this case El Instituto de Higiene Rafael Rangel, would have to be delimited and specific since the very beginning in order to avoid overlaps of competences between the SAPI and IHRR, or the veto power from one institution to the other.

The Chilean strategy of protection for intellectual property rights, given the current political trends in the country, will not be accepted or even applicable. If the country is struggling to implement minimum standards of protection, then

¹⁰²⁶ The relation is \$1,00 = Bs. 6,3, and the parallel market exchange for this week was stimated at \$1,00 = Bs. 78,00.

implementing higher levels that in principle were to benefit foreign companies would definitely not be aligned with the actual governmental line.

To be fair, intellectual property rights seemed to have been forgotten in Venezuela. The country withdrew from the Andean Community in 2006, and the Andean community framework was in force until 2010. Since then, almost 4 years have past and the patent system is still out-dated. The sanctions imposed on Brazil in 1989, and the posterior consultations before the DSB on behalf of the United States for the implementation of Prior Consent, give weight to the belief that Venezuela should have been brought before WTO for breaching TRIPS. The fact that nothing has happened since the legislative debacle with the Andean Community suggests that commercial interest may also play an important role in the relations between Venezuela and other trading partners. Regardless of political and commercial interest, Venezuela could benefit greatly from implementing a health care system similar to the one available in Chile, or even the Brazilian strategy as long as consistence and continuity are achieved. Currently, three health care systems are 'running' in parallel: the public, the private and the Bolivarian system Barrio Adentro.

The government is trying to control prices via all possible legislative solutions, as if this is the main factor challenging access to affordable medicines in Venezuela. However, the system is running out of funding and several clinics have threatened to close their doors since they are not able to provide health care services.¹⁰²⁷ Laboratories are also in trouble, since the government has also regulated their prices; lab supplies are imported and not produced nationally. Therefore, clinical labs are also struggling to have access to preferential currency to purchase supplies.¹⁰²⁸

The term *access to medicines* encompasses the array of problems faced by the world's lowest-income habitants, who often cannot afford, or do not have access to, medications that could greatly reduce the disease burden under which they suffer. The problems include **deficient medical infrastructure, imbalances between prices and ability to pay, and the lack of incentive to develop medicines** that would treat diseases endemic to low-income nations¹⁰²⁹

High levels of bureaucracy, corruption and even over legislation contribute to the economical chaos prevalent in Venezuela. Despite the country's investments in the public health care sector, the facts that there are three systems running in parallel, that there is unequal distribution of resources and that there is no intention in unifying the systems to achieve a better performance, all seem to dilute any efforts in providing universal coverage. For instance, there is a health programme within both IVSS and the Barrio Adentro health centres that provide free or affordable medication for those diseases identified in the country as costly and catastrophic. However, lack of information and impartiality challenges citizens' access to affordable, essential medication.

¹⁰²⁷ 'Sociedades Médicas en emergencia por regulación de precios de en clínicas' *El Carabobeño*, 14 de Julio de 2013

¹⁰²⁸ Moreno Sucre, J., 'Advierten del cierre de 70% de los laboratorios clínicos' *El Universal*, 9 de Julio de 2013

¹⁰²⁹ Scherer, F.M., 'Essential Drugs' (February 2007) *KSG Working Paper No. RWP07-003*, 1-11, 2<ssrn.com/abstract=939659 or <http://dx.doi.org/10.2139/ssrn.939659>> accessed 4th April 2014

In the Venezuelan context it is not possible to infer that either pharmaceutical patents or patents in general have had a negative impact on the economic or national development. On the contrary, development began deterring about the same time the IP Law from 1955 was re-implemented. Reportedly, no pharmaceutical patent has been granted since 2008, and during 2009 the Patent Office began rejecting patent applications. The Patent Office Journal from November 2009 states that from 200 patent applications in total, 65 were related to pharmaceuticals and all of them were returned due to administrative requirements, only to later on be rejected again.

The situation in Venezuela is far from easy; several other challenges need to be addressed soon, among them staggering inflation rates.¹⁰³⁰ Money control policy is an interesting and complicated component of the Venezuelan strategy.

Asserting that in Venezuela pharmaceutical patents pose an obstacle for people's access to medicines only seems to be out of context and misleading. Recent trends, or those followed in the last 14 years, indicate otherwise. With no concise health care provisions, no continuity within the goals settled by each elected administration with regard to regulation of prices and services, poor infrastructure, lack of human resources, bureaucratic procedures slowing down administrative processes and consultation in my opinion would pose a heavier burden policies related to access to medicines in Venezuela than protecting pharmaceutical patents *per se*.

Both health care and intellectual property provisions need to be developed in synchrony and harmony –implementing TRIPS flexibilities and efficient public procurement practices - if the country really aims at having a patent system that in the long run will favour both the national industry and that will ensure people's access to affordable and top of the line medicines. Solidarity, continuity and accountability seem to be the elements conveying governmental success in implementing health care policies addressed to achieve access, affordability and availability of essential medicines while at the same time implementing IP policies addressed to foster innovation.

7.1.4. Other General Suggestions: Developing a Side System to Create Incentives for R&D on Neglected Diseases

Despite the conclusions and suggestions presented above within a specific context, there is another set of suggestions that could be applicable in the general context of patents and access to medicines and the access to the discourse on medicines. Thus, the present discussion aims at addressing the solutions within the context of neglected medicines. The little amount of R&D on neglected diseases might also be linked to the market size for which the pharmaceutical product is intended. Michael Kremer in 2002 analysed how companies are driven by the market size to develop and commercialise a specific product.¹⁰³¹

¹⁰³⁰ 'BCV reporta una inflación acumulada de 42,6% en los últimos 12 meses', *El Nacional Web*, 6 August 2013

¹⁰³¹ Kremer, M., 'Pharmaceuticals and the Developing World'(Autumn, 2002) 16 *The Journal of Economic Perspectives*4, at 67 – 90

Developing a new drug has also proven costly: approximately \$800 million was spent by the pharmaceutical industry in 2006 when carrying out this task,¹⁰³² and it is also estimated that “less than 1 per cent of the new chemical compounds examined are used in human testing”¹⁰³³ which is part of the factors increasing R&D costs.

Given the crisis in supplying certain markets with affordable medications or effective medicines post TRIPS Agreement, scholars have argued the inefficiency portrayed by the patent system in solving or addressing a solution to lower the price of essential medicines.

A couple of suggestions or solutions outside of the legal framework (compulsory licences) have been presented, such as out-licensing or prize founded research in an attempt to find a balance between private and public interests.

It is commonly found that perhaps the best solution to lower pharmaceutical prices, hence, increasing access to essential medicines, would be to leave the pharmaceutical industry and the generic industry to compete in the market.¹⁰³⁴

Free competition could be a good way to lower the price of medicine, except in those countries i.e. Chile where free competition has proven to worsen the situation for the small size pharmaceutical industry and pharmacies trying to survive in the market.¹⁰³⁵ However, more likely than not, only a few would debate on patents being the successful mechanism to recoup R&D investment.

7.1.5. Suggestions for a Side or Parallel System

A possible solution to prompt innovation and R&D in the field of neglected diseases, is a prize award model. This model is suggested by Joseph E. Stiglitz, who believes that a medical prize fund would function as a better incentive than the patent system itself, in order to reward the discovery of a cure or treatment

¹⁰³² Civan, A., et al. ‘The Determinants of Pharmaceutical Research and Development Investment’ (2006) 5 *Contributions to Economic Analysis & Policy* 1, Article 28

¹⁰³³ Idem

¹⁰³⁴ This could only happen once the patent has expired. Another way to guarantee lower prices for certain medicines is generally achieved through prices control policy, although this might deter innovation. For a further insight see, WHO- Commission on Intellectual Property Rights, Innovation and Public Health “Public Health, Innovation and Intellectual Property Rights”, in Report of the Commission on Intellectual Property Rights, Innovation and Public Health, at 116

¹⁰³⁵ Between 2007 and 2009 two of the most renowned pharmacy branches in Chile started a so-called “price war” by reducing prices of certain pharmaceutical products. This business decision allowed them to compete for a better positioning within the Chilean Market, but it lead to many small and medium sizedsize pharmacies to almost go out of business, because it was not possible for them to keep up with the bigger franchises. Later on this case reached the Competition Court, due to collision agreements with producers. The case is still in Court and further information about this will be available at the Chilean chapter of my thesis. But you can also see El Mercurio, “La Pelea de Cruz Verde y FASA por adueñarse del concepto de bajos precios” from October 9th, 2007. Also available at <www.economiaynegocios.cl/noticias/noticias.asp?id=34637>. Also see El Mercurio, “Grandes Farmacias Registran hasta una diferencia de precio del 78% por un mismo remedio” from May, 21st, 2009, <diario.elmercurio.cl/detalle/index.asp?id=%7Bb3991d5b-ce65-43f4-8101-96f5e116a2e8%7D>

for a neglected disease. A prize fund could allocate enough resources for the R&D of those diseases that the current patent system has not been able to incentivise.¹⁰³⁶

The aforementioned model comes as a parallel solution to the patent system. The prize fund system focuses on promoting research on neglected diseases, and ideally once the discovery¹⁰³⁷ is made this would be licensed.¹⁰³⁸ It is no secret that pharmaceutical industries do not only spend considerable amounts of money on R&D, but also on marketing campaigns. It is precisely the resources spent on marketing and the invention of lifestyle drugs¹⁰³⁹ that forms Stiglitz's main arguments against the pharmaceutical industry's current behaviour: the pharmaceutical industry focuses on recouping R&D through commercialisation of lifestyle drugs which generally are in fashion.

A couple of challenges have been identified in relation to this method. First, prize issues: how much would the prize be worth? Would the sum settled be enough to actually be duly noted by the pharmaceutical industry? How much will be enough? Up to 2001, the pharmaceutical industry spent about half a billion dollars on developing a new drug; from 5,000 compounds used, maybe only one would be successful.¹⁰⁴⁰

Secondly, it is suggested to have a skilled body (Scientific panel) evaluating the claims. But who will be part of this skilled body? Besides settling a prize fund, what are the conditions applicable for winning and claiming the award? Is it enough to just raise the awareness of the Scientific panel about the invention? Who would be part of this scientific panel? How would it be structured?

Third, commercialisation and marketing approval issues that will be necessary to fulfil if a product reaches the market. For instance, if the pharmaceutical industry finds a prize fund as an incentive to engage in R&D of a needed drug, then pharmaceutical company in any case will also have to go through the national mechanisms before supplying the market with the affordable drugs. This means that in complying with quality, clinical trials and all the safety requirements will be necessary before either applying or receiving the marketing approval for a new drug.

¹⁰³⁶ Stiglitz, J., 'Prizes, Not Patents' in *Project Syndicate*, 2007 <www.project-syndicate.org/commentary/stiglitz81/English> accessed 21 June 2010

¹⁰³⁷ An important remark shall be made regarding Stiglitz's assumption on the patentability of a discovery. Discoveries are not patentable, but inventions are. Although there is no reference made by the author as to whether or not the invention adjudicated with the award will claim patent protection, the author mentions the possibility of licensing such an invention. Hence, it could be assumed that the author refers to a discovery as a synonym of an invention that in law is not correct. Nevertheless, Stiglitz offers a possible side solution to promote innovation of R&D of certain diseases, but this method needs further development, as there are many things unaddressed

¹⁰³⁸ Is ut Supra Stiglitz at 9

¹⁰³⁹ Lifestyle drugs are considered to be those to treat none life threatening conditions. Definition taken from Stiglitz quoted above

¹⁰⁴⁰ Love, J., 'How Much Does it Cost to Develop a New Drug' in Draft on consumer Project on Technology, 2000 <www.cptech.org/ip/health/econ/howmuh.html> accessed 23 June 2010

Scholars have also assessed alternative incentives, other than patents. Therefore, several models have been analysed and among them are the pull and push models, which seek to reform or replace TRIPS.

The push model seeks to encourage R&D by using public funds to invest in research either by public or private institutions; and the pull model seeks to encourage innovation by offering prize or some other financial incentive.¹⁰⁴¹ Whilst taking into consideration these two models, Odermatt assesses the bureaucracy and financial burden brought about by the patent system, which in his opinion is a pull model in itself. The scholar also highlights that the push model seems to encourage R&D on finding a cure for certain diseases which will be better than leaving to the market the possibility of coming up with a solution at some point. This model portrays a compatibility problem with the patent system since the structure of the pull model seems to convey more. In other words, the risks undertaken by either of the models vary and so does the burden undertaken by the parties involved. In one case the higher investment risk is for the fund and or the financers of the Research, and in the other the risk is for the different companies racing to find a cure. Since one of the parties will bare higher risks and costs than the other one will.

One of the suggestions is to create alternative incentives for R&D of new drugs for neglected diseases is the creation of a pull prize system. This indicates, that if the prize system is based on the therapeutic benefits portrayed by the drug, this alone will provide enough economic incentive for the pharmaceutical companies to invest in the creation of drugs for neglected diseases, and most likely it will allow the generic industry to sell the drugs at more affordable prices.¹⁰⁴²

The other solution presented at the beginning of this heading was the out-licensing option, which consists of giving a voluntary licence to generic manufacturers who would agree in only manufacturing and supplying medicines to the least developed and developing countries.¹⁰⁴³ These legally binding agreements will allow generic manufacturers to compete with each other in the least developed and developing countries, but they will not allow them to compete with the original patent holder in richer countries. Hence, prices will be lowered considerably due to competition and the incentive to keep R&D of new drugs will not be deterred. This approach has a couple of drawbacks, since there is the need to have nonexclusive licence rights to really promote “free competition”; most likely companies will reduce their presence in the markets of the developing countries. Secondly, the success of this mechanism will depend on economic conditions determined by the market itself and not the company out-licensing, which in other words could deter interest in out-licensing agreements if there are not many buyers for the product due to massive amounts of money provided by foreign aid to treat a specific disease. This will probably deter generic

¹⁰⁴¹ Odermatt, J., ‘Investigating New Models of Pharmaceutical Innovation to Protect the Human Right to Health’ (2009) 40 *The International Review on Intellectual Property and Competition Law* 2, 173-181

¹⁰⁴² Ibid

¹⁰⁴³ Friedman, M., den Besten, H., and Attara, A., ‘Out-licensing: a practical approach for improvement of access to medicines in poor countries’ (January, 2003) 361 *The Lancet*, at 341 -344

manufacturers' interest in reaching out-licensing agreements with pharmaceutical products to supply needed markets.¹⁰⁴⁴

These out-licensing agreements shall take into consideration specifically the definition of which medicine, country, enforcement measures and legal rights are to be granted and the royalties.

Having said this, it is necessary to define how this mechanism would work, if it has been used, who has used it and which medicines could actually be out-licensed.

Pharmaceutical companies such as Glaxo Smith Kline, Boehringer Ingelheim and Bristol-Myers Squibb have used this mechanism in the past to help supply the market of South Africa. Accordingly, this mechanism is a more encouraging option than compulsory licences. So far, some possibilities to create other incentives and the patent system to foster further R&D on neglected diseases have been assessed. Every suggestion discussed above brings a set of questions and perhaps challenges that need to be solved before having something more serious to present to the pharmaceutical industry.

Given that the situation in every developing nation may differ from that of another, and that access to essential medicines it is not solely dependent on patents, further incentives may need to be considered. However, when assessing the public health discourse, there are a couple of issues that need to be analysed separately. If it is widely accepted that access to medicines is part of the human right to health, then it is also very important to stress the duty of governments to protect public health needs, which most likely vary from country to country. Therefore, the duty in guaranteeing access and affordability does not rest alone on the pharmaceutical industry's decision-making power. The pharmaceutical industry must guarantee availability in the sense of production, but the governments must negotiate if necessary to guarantee affordable prices for essential medicines.

For some tropical countries, that also happen to be developing nations, dengue medication belongs to the chart of their essential medication. However, since this one also falls within the neglected disease category, it is the author's opinion that perhaps these nations should provide wider incentives for R&D at universities. Perhaps a way to create further incentives would be to allocate more resources to local talent that would possibly lead to a manufacturing capability to supply the internal market without depending exclusively on private interests.

Striking a balance between patents and access to medicines has proven controversial. Neither compulsory licences or parallel imports seem to be widely accepted mechanisms providing a solution to the problem, and perhaps there will not be a single solution along the lines of "one size fits all". Perhaps the issue is to assess and tackle the crises individually within the globalised and standardised system. Therefore, it seems only appropriate to stress the need to tailor the TRIPS Agreement implementation within the national contexts.

Price competition is not possible until immediately after the patent has expired. So how can prices be driven down without affecting the pharmaceutical industry's

¹⁰⁴⁴ Ibid

interests (profitability and recouping the investment)? Could this be achieved via direct negotiations between the governments and the industry? What about public – private partnerships? Currently there are a couple of NGOs allied with the pharmaceutical industry which follow WHO's recommendations in fighting and providing treatment for neglected diseases.¹⁰⁴⁵ So far the Partnership for Diseases Control initiatives and the Task Force for Global Health seem to be having great success in fighting some of the tropical and neglected diseases afflicting the Developing world. However, it is also known that further donations will be required in the future to keep on going with these programmes. The question remains as to which is the adequate system to foster R&D for neglected diseases?

Within the idea of creating a side system of incentives, the possibility of creating different sources of funding for either R&D or raising money to purchase cheaper medication on amass scale or in bulk procurement also comes into the spotlight. The model followed by UNITAID country members is actually very interesting, since the funding for the organisation comes from levying taxes on flights. A short flight in economy class is deemed to give up to 1€ and a long-haul flight departing from any of the countries in business class can raise up to 40€; hence, a full flight between London and New York is said to raise enough money to cover a years treatment of 60 HIV-positive children. Other countries, part of the organisation, are committing multi-year budgetary contributions.¹⁰⁴⁶

Despite the model chosen to create further incentives to foster R&D, it is important to remember that a reward system for the inventors' efforts in giving society a solution to a problem should exist. The cases of Brazil and Chile show the importance in both guaranteeing access to medicines while at the same time protecting intellectual property rights. Moreover, both systems also demonstrate the efficacy of setting long-term goals within the government and policymaking mind-set. In other words, independent of a determined administrations' ideology, if a system is not set forth to be on-going and in solidarity with the country's needs, then most likely any legal reform will not solve the public health care challenges or private interests (patents) prevalent in that country.

Admittedly, the issue at stake is complex and providing a single applicable solution is not possible since every country has a different set of needs. Therefore, it is important to reiterate that in the case of Venezuela, the possible solution is to reform both the patent and the health care system in a manner consistent with the country's needs. For instance, if we start from the assumption that the current issues related to the access to foreign currency do not exist, and that the economy in the country allows the normal development of the industry in general, then hypothetically the only issue at stake in terms of access to medicines is to balance the patent system. So, a possible solution could be presented as follows:

- Two legislative reforms would be necessary. On the one hand, bring the current IP system into compliance with the TRIPS Agreement, but do so in a manner similar to the Brazilian system: curve the negative effects by taking into consideration the country's needs and make use of the flexibilities provided within the Agreement i.e. compulsory licences and

¹⁰⁴⁵ Gustavsen, K., et al. 'Progress in Public-Private Partnerships to Fight Neglected Diseases' (Nov/Dec 2009) 28 *Health Affairs* 6 at 1745

¹⁰⁴⁶ Id ut Supra, Jorge Bermudez and Ellen 't Hoen

parallel imports. On the other hand, a reform within the public health sector deems it necessary to unify the current systems running in parallel –for organisation and clarity’s sake. In doing so, the priority health concerns within the country may be identified to thereafter actually make use of the flexibilities to guarantee access to affordable medicines. However, it is important to stress the fact that the health reforms, as stated, may be simplistic. Thus, it is my belief that such a reform will need to be carried out in at least three to four stages. The utmost priority is to identify health needs requiring pressing attention due to the severe consequences for the society; regardless of whether these are related to epidemics, catastrophic diseases or high cost medicines. In doing so the government will be able to implement public procurement practices to obtain better prices, and if necessary increase bargaining power by threatening to use compulsory licences. Once the priorities have been identified it will be also necessary to implement protocols and guidelines for treatment and diagnosis to be followed by practitioners, together with massive education and media campaigns to reach out to the public about the illnesses and also to inform them about the existence of such programmes. Admittedly, some of these exist in Venezuela, however, the analysis showed how critical the lack of information is for patients to either access the programmes or even know about their existence. Even though practitioners are nowadays compelled to use the generic versions or even prescribe medicines by their active ingredient, it is important to educate patients and demystify the use of generic medicines. Within the stages of reform it will be also suggested to increase the levels of efficiency and effectiveness of the health agencies granting marketing approvals.

The Brazilian analysis showed that the implemented health policies were drafted in a manner that patent rights would not prevent the country from providing access to affordable medication, and in the cases where patents would seem to interfere or become an obstacle it was the IP Code providing the exception to grant patents. Whether or not the prior consent mechanism is compatible with the Brazilian Constitution, its implementation seems to address fulfilling the social function enshrined within the constitutional text. Acknowledging the disparities would only serve as an example for other countries trying to implement a similar system in terms of solving or making it work within a determined context. Beyond implementing a solution similar to that in Brazil or Chile, it is important to stress the common factors between these two countries in terms of patent protection and access to medicines i.e. investment, consistency, solidarity, political will and civil society’s activism. Another aspect of utmost importance is to create a mechanism ensuring transparency and fairness when using procurement practices, designing distribution and the logistics when bringing affordable medicines to both patients and the market. Without rational use of the resources, at all level involved, the health care system would most definitely destined to fail. Intellectual property rights hand in hand with public health reforms could contribute with the country’s development.

Given that the author is of the opinion that pharmaceutical patents have not influenced or directly deterred access to medicines within the Venezuelan context, the author has given as a possible solution the reforming of the IP Law from 1955 according to the minimum standards of protection settled within TRIPS. Thus, this reform and implementation should take advantage of the provisions allowing the country to address the access, innovation and

affordability of medicines given that the current model is not working. In doing so, Venezuela would ensure that both IP rights and access to medicines are somewhat balanced within the country.

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DHANAY MARÍA CADILLO CHANDLER

THE ROLE OF PATENTS IN THE LATIN AMERICAN DEVELOPMENT: 'MODELS OF PROTECTION' OF PHARMACEUTICAL PATENTS AND ACCESS TO MEDICINES IN BRAZIL, CHILE AND VENEZUELA

Access to medicines, pharmaceutical patents, and public health are topics often addressed in the news. On the one hand, there is an imperative need to tackle pressing health concerns, and on the other hand, it is also important to provide adequate incentives to carry out research and development. Even though common health concerns exist within the developing world, each country has a different set of needs. The approach to solve or the strategies to balance intellectual property rights and access to medicines vary at large. Latin American countries i.e. Brazil, Chile and Venezuela, even though geographically located in the same continent, deal with the challenges in a different and unique manner.

Before the TRIPS Agreement countries had the freedom to decide on whether or not to grant patent protection for medicines. Thus, most of the developing and least developed countries, now WTO member countries, did not provide patent protection for pharmaceuticals because they feared that patent protection would increase the price of pharmaceuticals, and hence, become an obstacle for the access to medicines.

On the one hand, patent protection represents an incentive for the pharmaceutical industry to carry out R&D for new and needed drugs. But on the other hand, patents, as the system of financing R&D, has been regarded

as a flawed system due to the high costs transferred to the finalised product (medicine) thus deterring access to medicines. Patent protection allows the inventor to prevent others from making use, selling, producing or distributing the invention without his consent for a period of no less than 20 years. Moreover, these rights conferred by the patent grant seem to constitute the pharmaceutical industry's incentive to recoup the high costs associated with the R&D of a new drug.

This book reviews the strategies or models of protection used in Brazil, Chile and Venezuela to balance both intellectual property rights (pharmaceutical patents) and access to medicines. Each country seems to have shaped their policies in accordance with their national priorities, whether these are motivated by health, political or commercial issues. This study portrays the different approaches followed in different national contexts despite all three having to implement the minimum standards of intellectual property protection according to the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The outcome of the comparison of the policy implementations and the patterns followed by each of the analysed countries is without a doubt the main contribution of this academic study.



ISBN 978-952-232-237-1 (printed)

ISBN 978-952-232-238-8 (PDF)

ISSN-L 0424-7256

ISSN 0424-7256 (printed)

ISSN 2242-699X (PDF)

EDITA PRIMA LTD, HELSINKI



9 789522 322371

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